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Master's Degree in Biomedical Engineering

Thesis

Different approaches to improve the healthcare in Africa through Biomedical Engineering

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Nomenclature

ABEC African Biomedical Engineering Consortium

AIMDD Active Implantable Medical Device Directive

ANDI African Network for Drugs and Diagnostic Innovation

ARSO African Organization for Standardization

AU African Union

BME Biomedical Engineering

CAB Conformity Assessment Body

CAMTech Consortium for Affordable Medical Technologies

CDC Centers for Disease Control and Prevention

CE Conformité Européenne

CoRSU Comprehensive Rehabilitation Services for Uganda

DGPML Directorate Generla of Pharmacy and Drug Laboratories Government

DoC Declaration of Conformity

DoH South Africa department of health

DSP Digital Signal Processor

ECUREI Ernest Cook Ultrasound Research and Education Institute

EDA Egyptian Drug Authority

EFTA European Free Trade Association

ERC Essential Requirements Checklist

ERs Essential Requirements

EU European Union

EWH Engineering World Health

FDA Food and Drugs Authority

FDM Fused deposition modeling

FMHACA Food, Medicine and Healthcare Administartion and Control

GHTF The Global Harmonization Task Force

GMDN Global Medical Device Nomenclature

GMDN Global Medical Devices Nomenclature

ICD International Classification of Diseases

IMDRF International Medical Device Regulators Forum

IR InfraRed

ISO International Organization for Standardization

ISS Innovators' Summer School

IVDMDD In Vitro Diagnostic Medical Device Directive

JICA Japan International Cooperation Agency

MDD Medical Device Directive

MDGs Millennium Development Goals

mHelath Mobile Helath

NAFDAC National Agency for Food and Drug Administration and Control

NDA National Drug Authority

NGO Non-Governamental Organization

NHS National Health System - England

NRA National Regulatory Authorities

NTIS New Technologies and Innovation Section

OSD Open Source Definition

OSHWA Open Source Hardware Association

OSHW Open Source Hardware

OSI Open Source Initiative

OSS Open Source Software

PIR Passive Infrared Sensor

PMPB Pharmacy, Medicine and Posons Board

PPB Kenya Pharmacy and Poison Board

RA Regulatory Authority

RCT Reference Clinical Thermometer

SIDO Tanzanian Small Industries Development Organization

SLIPTA Stepwise Laboratory Improvement Process Towards Accreditation

STED Summary Technical Documentation

STL STereo Lithography interface format

TFDA Tanzania Food and Drug Authority

TUT Thermometer Under Test

UNECA United Nations Economic Commission for Africa

WHO World Health Organization

Introduction

There is no question that technology has played a key role in improving the quality and cost effectiveness of health services as well as access to healthcare facilities. Technology is at the heart of effective healthcare services helping medical and paramedical personnel in all stages of their work: from prevention to diagnosis, treatment and monitoring. Yet, technology entails huge investments in economic, physical and human resources.

Development experts have long recognized health as an important social goal. Health is also a component of a development strategy, along with education, economic growth and good governance. As a form of human capital, health is essential to a productive society.

Good health is a complex state and its achievement requires much more than just one or two interventions, but an integrated range of preventive strategies; environmental changes, therapies and technology to diagnose and treat ill health, and provision of opportunities for those who need healthcare to access it. A good partnerships between communities, providers, organizations carrying out governments interventions, technical agencies and international partners is necessary.

Health technologies are an indispensable component of effective healthcare systems. Among these technologies, medical devices provide tools to treat and rehabilitate people living with illness and disease. The World Health Organization (WHO) cites over 10000 existing medical devices ranging from lancets to complex imaging equipments, in vitro diagnostic and implantable devices. Although medical devices are readily available, few countries in Africa can afford to purchase or use them, mainly for their high cost that is not sustainable by their economy. In developing countries over 95% of equipment is imported but most of it is inappropriate for local needs and unable to be sustained due to the lack of local infrastructure. Nearly 80% of imported healthcare equipment is donated or funded by international donors or foreign governments. Although donations are often made with good intentions, the outcomes are not always positive if

the donations are not properly planned and coordinated. The WHO estimates that only 60% of the donations are put into operation; reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training and lack of effective technical support. However, in one of the very few prospective studies Robert Malkin, a professor of the practice of biomedical engineering at Duke University, showed that 66% of out of service equipment could be returned to service using only locally available materials and less than $50.

A lack of Biomedical Engineering education and practice in developing countries is evident and it makes impossible to have cohorts of biomedical engineers which focus on the issues in their own countries. Many solutions to overcome the lack of medical devices have been put forth; these ideas have ranged from aggregating markets, to increasing donation regulation and improving capacity building of students and technicians.

The majority of countries in Africa do not have a health technology national policy. The regulatory agencies for medical instrumentations, where these are available, often present a physical lack of staff for consultation. This is a problem for people who want to produce, sell, or even donate these devices. This lack, often linked to the missing institutions and political organizations, represents a problem for the population since lots of inadequate and sometimes dangerous devices are put in the African markets without quality and safety controls.

A possibility to improve the situation is to develop and implement an affordable and sustainable healthcare system based on recognized policies and regulations. Another possibility is related to the reduction of costs of medical device, through an Open Source Design (sharing design, documentation, source-code, ideas and data) but maintaining the quality unaltered through the compliance with the standard. Another essential approach will be training biomedical engineering students and technicians in design, maintenance, evaluation, and also repairing medical equipments. This training can be achieved by providing study programs and can be constantly improved by performing summer schools on specific topics.

The thesis work has been developed in the framework of the African Biomedical Engineering Consortium (ABEC) and during the development phase of UBORA project that has been financed by European Union. UBORA's goal is an educational and design e-infrastructure for co-design of open source medical devices to address current and future global healthcare challenges that taking into account needs, safety, feasibility, efficacy and performance.

After an overview in Chapter 1 on the current state of healthcare in Africa, with particular regards to the condition of medical devices, Chapter 2 talks about the status of medical device regulations and their harmonization as solution to improve the healthcare in Africa. Particular attention was given to ABEC countries.

In Chapter 3 the use of the Open Source Medical Devices to improve the healthcare in Africa was taken into consideration. The Open Source advantages such as its accessibility, sustainability, lower costs are evaluated through two examples: InfraRed (IR) contactless thermometer, that has been used as teaching tool during the Innovators' Summer School 2016 in Ethiopia to which I took part, and 3D-printed spectacles. These two medical devices are designed and built considering some critical aspects for developing countries as cost, availability of materials and easiness of construction. These features have been collected in ranking table, to quickly evaluate the project from a designing, construction, feasibility and usability point of view.

Since there is no medical care without medical equipment, the opportunities of second-hand sale, are discussed in Chapter 4, which describes my training period at Hilditch Group in Malmesbury, England, where I learned about the market, maintenance and repair of medical devices checking their conditions and attending to auctions to the sale of several medical devices. Always the Chapter 4 describes a period with the Amalthea Trust charity in Uganda to teach to biomedical technicians at Kyambogo University, in Kampala, about the repair of medical devices. The aim of the training was to provide help for the sustainable maintenance of medical equipment through the provision of training programmes for the recipients, including test equipment and workshop. To address the ever increasing requirement in identifying, sourcing, installing, customizing, servicing and upgrading of advanced medical devices and other technologies the need of highly qualified personnel can not be underestimated.

The evaluation of donated medical equipment and devices, is discussed in Chapter 5. This is based on the direct experience of visiting three different hospitals in Uganda. The results have been used by Amalthea Trust in order to have a better idea about the condition of donations and to develop a training programmes and train personnel related to their real necessities.

Finally to understand the needs and personal opinions about the condition of medical devices in Africa surveys was collected, in particular during the period in Ethiopia and Uganda, which results are discussed during the thesis.

CHAPTER 1

The state of healthcare in Africa

Healthy people are more productive, and healthy infants and children can develop better and become productive adults. A healthy population can also contribute to a country's economic growth. Increased investment in health would translate into hundreds of billions of dollars per year of additional income, which could be used to improve living conditions and social infrastructure in poor countries. It is estimated that for every 10% increase in life expectancy at birth there is a corresponding rise in economic growth of 0.4% per year.

1.1 The Cycle of poverty and ill-health

People living in Africa face a heavy and wide-ranging burden of disease, which takes its toll on social and economic development and short-end their life expectancy. The HIV/AIDS epidemic as well as the malaria and tuberculosis have swept away improvements in life expectancy [1] in some sub-Saharan countries, see Figure 1.1 [2]. Other infectious diseases and, increasingly, no communicable conditions are also a severe burden, while the complications of pregnancy and childbirth take millions of lives every year.

The health services that have evolved in African countries are often not able to address adequately this severe burden of disease. These health systems are weak, reflecting the overall state of the economies in Africa.

In many countries medical bills are high in proportion to household incomes and are a major factor of poverty. The cost of treatment for an adult with HIV/AIDS in addition to lost income due to time off work can drag a whole household below the poverty line [3]. Therefore, just as health can drive economic growth, ill-health can push people into poverty and make it very difficult for them to escape the poverty trap. The cycle of poverty can be seen in many countries in

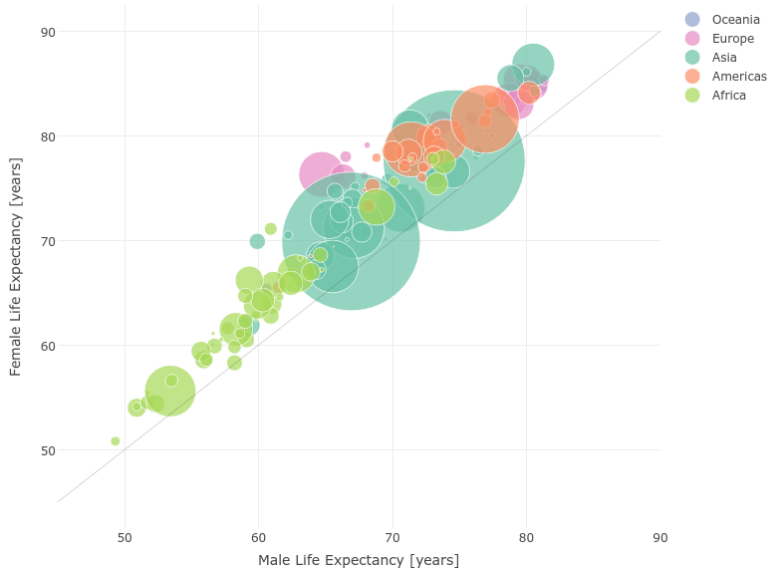

Figure 1.1: Life expectancy at birth

Africa. About 76% on population of sub-Saharan Africa live less than US$ 2 a day and 46.5% on less than US$ 1.08 a day, see Figure 1.2 [4].

While poverty has declined in other parts of the world, such as East and South Asia, in Sub-Saharan Africa the trend has been the opposite. The trend is likely to continue, with poverty expected to decline over the next 20 years in every part of the world except sub-Saharan Africa, where a dramatic increase is expected.

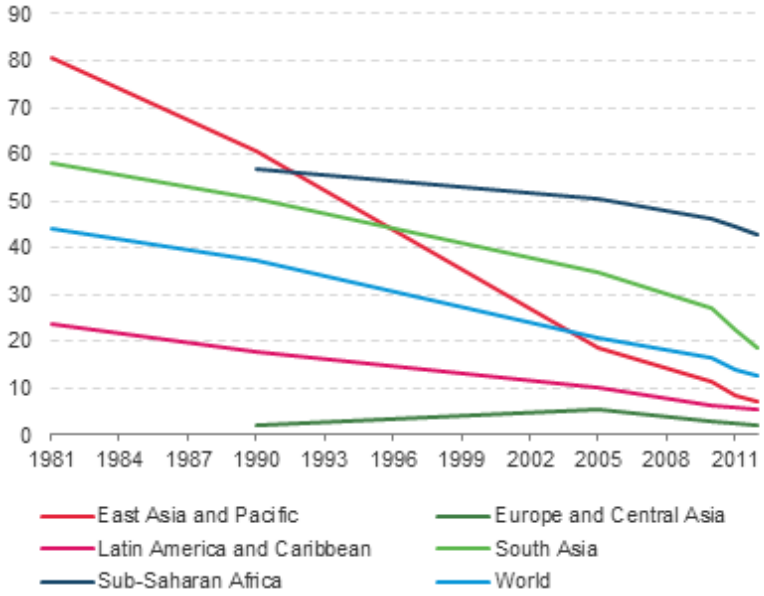

Figure 1.2: Share of population living in absolutely poverty

Economic growth has not always led automatically to improvements in pub-

lic health in the African Region. Current growth rates are an opportunity for African governments to invest more in health, an investment that would lead to more social and economic stability [5]. Increased investment in public health can reduce the burden of preventable and treatable diseases that on macroeconomic level can be a drag on national economies and on microeconomic level a drain on household and individual incomes.

Health must, therefore, constitute a central pillar of any coherent vision of African development, while increased investments in health should include those in health-related sectors, such as water and sanitation, education and environmental protection.

In Figure 1.3 we can see the complex pathways in which health contributes to economic development [6]. A recent study concluded it is more likely for countries to experience virtuous cycles of economic development, or positive economic growth cycles, if they first experience virtuous cycles in human development, such as improvements in health status [7] [6].

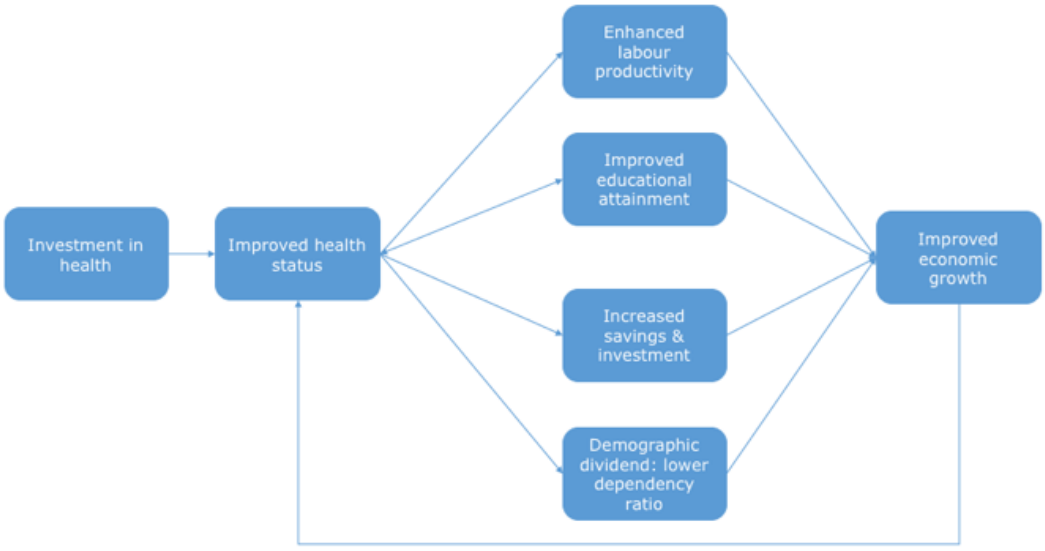

Figure 1.3: Investment in health contributes to economic development

Development experts have long recognized health as an important social goal. Health is also a component of a development strategy, along with education, economic growth and good governance. As a form of human capital, health is essential to a productive society. Furthermore the Millennium Development Goals (MDGs) project of the United Nations fully endorses the central role of health in the development [8].

At the country level, health status is an important marker of economic development as measured by life expectancy or other health indicators; in many respects, initial health of a population seems to be a better predictor of subsequent economic development than is initial education [5].

1.2 Working together to achieve health for all

There are many regional and international initiatives to promote development in Africa. Some have focused on health as well as education, governance and economic policy, while others have focused entirely on health. In recent years both governments in Africa and donors have pledged to provide more money for health and development [9].

Good health is a complex state and achieving it requires much more that just one or two simple interventions, but an integrated range of preventive strategies; environmental changes, therapies and technology to diagnose and treat ill health, and provision of opportunities for those who need health care to access it. A good partnerships between communities, providers, organizations carrying out interventions governments, technical agencies and international partners is necessary[10]. Given the substantive proportion of external resources on health as a percentage of total health expenditures [Figure 1.4] the number of initiatives and the multiplicity of actors involved in health development in Africa, coordination and harmonization effort is essential to avoid waste and target real needs [10].

In many countries in Africa, health systems have been weakened by the ravages of war, economic crises and debt, among other things, that have led to drastic loss of staff and failure to maintain buildings, technology and supplies.

However in the past decade, enormous efforts by governments, international partners, technical agencies, researchers and other stakeholders committed to improving the health of the African people have been applied in strengthening their health systems [11]. Difficult geography, lack of specialist health-care workers and poor infrastructure make it difficult to deliver the preventive diagnostic and curative service people in Africa need to achieve good health. The elements needed for a functioning health system are:

- leadership and governance,
- human resources,
- health financing,

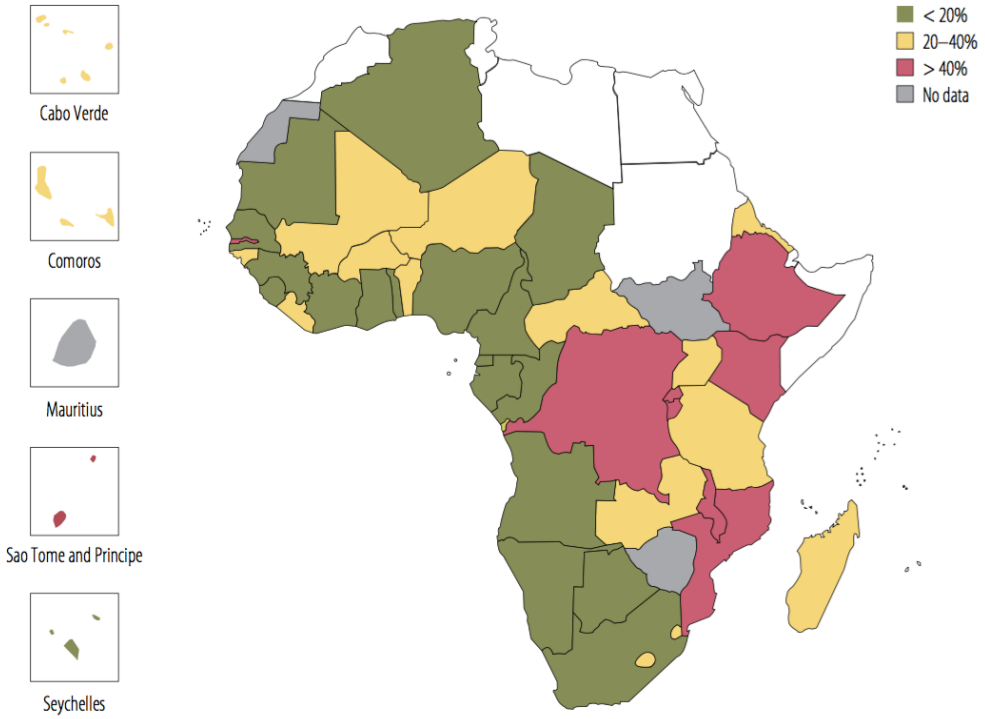

Figure 1.4: External resources on health as a percentage of total health expenditure in the WHO Africa, 2012

- information and research,
- access to medicine,
- medical devices,
- service delivery.

1.3 Condition of medical devices

Medical devices are articles intended for use in the diagnostic or cure, mitigation, treatment, or prevention of diseases or abnormalities in humans. Thus the term Medical device include different items from *"article, instrument, apparatus, up to machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose"* [12].

Health technologies are an indispensable component of effective healthcare systems. Among these technologies, medical device provide the tools to diagnose, treat and rehabilitative people living with illness and disease. WHO cites over 10000 existing medical devices ranging from lancets to complex imaging

equipment, in vitro diagnostic and implantable devices. Although medical devices are readily available, few countries in Africa can afford to purchase or use them. When devices are donated, appropriate use can still be a problem. There are gaps between needs and appropriate matching to conditions, and there is very little regulation governing the use of medical devices in the Africa [13].

There is a sever lack of safe and appropriate diagnostic imaging services in large parts of Africa. A large number of images are of poor quality and are of no diagnostic use. Many are also misread. In other areas imaging facilities are simply not available, or not functioning [14]. Thus, disease diagnosis is usually based on clinical conditions, unsupported by radiological evidence, and treatment may therefore be inappropriate or even dangerous. The challenges are lack of awareness, resources, equipment and qualified staff.

Functioning national health laboratory services rely on quality diagnostics, effective disease surveillance and prevention of major emerging, reemerging and endemic communicable and noncommunicable diseases [15]. In Africa, a shortage of qualified personnel, lack of essential laboratory supplies, infrastructure and equipment, and lack of national standards and systems for laboratory accreditation, proficiency testing, quality control and logistics are the main obstacles to early detection of epidemics such as hemorrhagic fever viruses (Ebola virus disease, Marburg virus, etc.) and both multidrug-resistant and extensively drug-resistant tuberculosis, among others. On the other hand, when laboratory or other diagnostic tools are available, incorrect interpretation of results is a common problem. There is a need for clear and comprehensive policies on health care technology.

For the past 14 years an external quality assessment program covering diagnosis of infectious diseases (HIV, tuberculosis and malaria) has been provided to many national public health laboratories in many countries of Africa by the WHO Regional Office for Africa with the technical support of the National Institute for Communicable Diseases in Johannesburg, South Africa [1]. Proficiency is tested and results shared with the laboratories, allowing them to improve diagnostic performance.

To further strengthen laboratory services in Africa, the Regional Office and its partners, including the African Society for Laboratory Medicine and *Centers for Disease Control and Prevention* (CDC), established the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA), a stepwise process that enables public health laboratories in developing countries to reach the ISO15189 standards that govern laboratory standards [16]. Laboratories develop and doc-

ument their ability to detect, identify and promptly respond to and report all diseases of public health significance that may be present in clinical specimens. SLIPTA started in 2012 with training of laboratory auditors and laboratory assessments. From 2012 to 2014, six laboratories in Kenya, Togo, Uganda and the United Republic of Tanzania have been accredited as having met ISO 15189 and 56 laboratories have been audited. More than 500 laboratories in Africa are on good track to meet ISO 15189 standards and accreditation [17].

Globally, the medical device market had an estimated worth greater than US$ 250 billion in 2010 [18]. Though the medical devices market has grown enormously over the past two decades, it is primarly concentrated in advanced healthcare systems of high-income countries and only minimally impacts the less advanced rural and primary care center of low- and middle- income nations. These devices have the potential to fulfill critical global health needs from rapid diagnostic testing to prevention and complex treatment. Supplying medical devices can involve transferring existing devices, also know as technological "diffusion", from developed to developing settings in the form of low-cost sales donations [19], [20].

In developing country, over 95% of the medical equipment in public hospitals is imported, with virtually no local production [21]. Most of the equipment is inappropriate for local needs and unable to be sustained with the lack of local infrastructure. In sub-Saharan Africa, 70% of existing equipment is not used, while *"at least half of all medical equipment in the developing world is unusable"* [22].

The lack of working devices in developing country is due to a multi-faceted system failure. It is necessary to highlight the main aspects that have created the present situation.

1. **Developed World Devices are too Expensive**
   Developing countries lack the funds to develop technologies to address their needs. Moreover, the costs of purchasing foreign device can be prohibitive for small, publicly funded clinics and hospitals. Device manufacturers know that they will never recoup research and development costs in developing countries, thus they do not even attempt to enter the developing world market knowing they will get minimal return on their investment.

2. **Lack of Supporting Technology/Infrastructure**
   While the shortage of medical devices is significant, one of the main obstacle to successful use of devices is the lack of supporting technologies and infrastructure. Unreliable electricity including spikes and brownouts, makes

it difficult to store vaccines that need to be refrigerated and necessitates expensive back-up generators and fuel to run them. Additionally, donated units may be incompatible with local power supplies of different voltages and frequencies than their countries of origin [22].

(a) **Lack of Human resources**
Recipients often lack the expertise and training to maintain, troubleshoot, and repair foreign devices [22]. This issue is particularly true for low-income countries where skilled labor is scarce, brain drain is common, and appropriate jobs for skilled engineers and technicians are hard to find and influenced by political, tribal, and regional affiliations and nepotism. Many devices designed in developed countries require specialized technicians and tools and are not built with the intent to be easily fixed with only basic tools [23].

(b) **Parts availability**
High-tech devices often require expensive replacement parts. Due to the rugged environments of most developing countries, the devices fail frequently and access to replacement parts is often difficult and expensive [23]

(c) **Financial burden of donated device**
A donated device may cost more to maintain and use than can be afforded, thus making the donated device a greater financial burden than help, especially if the scarce resources are needed elsewhere.

3. **Lack of Robustness**
Due to harsh environments (extreme temperatures, humidity, dust, etc.) in regions of many developing countries, devices that have been designed to operate in the sterile, climate-controlled work environments of many western medical facilities have very short life spans abroad. [23]. This is particularly true for devices that require biologics (e.g. blood, urine, live attenuated vaccines), all of which require refrigeration and frequent sterilization. These devices often fail due to the lack of necessary refrigeration and the biologics' short shelf life. The lack of capacity to maintain the devices further compounds problems due to misuse and neglect.

To understand the situation of biomedical devices in Africa and the differences between the different countries in Africa, Appendix A contains four tables, from the Global Atlas of Medical Devices drafted by WHO, of four different countries chosen as example, Egypt, Ethiopia, Uganda and South Africa [24].

1.4 Biomedical Engineering in Africa

Biomedical engineering is a discipline that advances knowledge in engineering, biology and medicine, and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice. It includes [25]:

- The acquisition of new knowledge and understanding of living systems through the innovative and substantive application of experimental and analytical techniques based on the engineering sciences.
- The development of new devices, algorithms, processes and systems that advance biology and medicine and improve medical practice and health care delivery.

There is a clear lack of Biomedical Engineering (BME) education and practice in developing countries. This lack of BME teaching institutions makes it clear that there are few cohorts of biomedical engineers in the developing world to focus on issues in their own countries [26].

Innovations in medical devices have played a major role in enhancing the diagnosis, treatment of illnesses, rehabilitation of the injured, comfort of patients and mobility of persons with disabilities and performance of complicated operations. Simple medical devices, such as thermometers and microscopes, have been at the forefront of the fight against malaria, while more sophisticated equipment, such X-ray machines, are important in the fight tuberculosis; the advances in medical devices have reduced the time and costs of detecting tuberculosis, increased access to rapid HIV testing kits and are eliminating the use of harmful chemicals through increased use of digital X-ray.

Many solutions to overcoming the lack of medical devices have been put forth; these ideas have ranged from aggregating markets [23] to increase donation regulation and oversight. While the most successful initiative is likely to take a system approach and combine many solutions, it is crucial that endogenous BMEs be the keystone of any steps moving forward. As Dr. Margaret Chan, WHO Director-General, stated **"progress in public health depends on innovation"**, and who knows the problems, available resources, and necessities of developing countries better than their residents? Figure 1.5 shows a group of Kyambogo's students during the Ultrasound training.

A particular case is South Africa which is the largest exporter of medical devices in Africa and is home to at least 160 companies operating in the medical de-

Figure 1.5: Ugandan students during the Ultrasound training

vice market. Of these firms, about 26 are local manufacturers, 68 distributors and 30 multinational firms. The top products of the industry include syringes, needles and catheters and electro-diagnostic devices and imaging parts and accessories, dental and irradiation devices. These products in total account for about three quarters of the industry's outputs.

1.4.1 Different approaches of Biomedical Engineering capacity building in Africa

There are a number of activities and programmes supporting Biomedical Engineering capacity building in Africa. Some activities are listed below:

- **Japan International Cooperation Agency** (JICA) has been building capacity of medical equipment management since 2000. They have trained technicians both in Africa and Japan, donated equipment and trained and supported users of various equipment.

- **The United Nations Economic Commission for Africa** (UNECA) [Figure 1.6] launched an initiative, "Promoting BME Youth Innovations for Improved Healthcare Outcomes in Africa", as part of the activities of the New Technologies and Innovation Section (NTIS).

- **African Biomedical Engineering Consortium** (ABEC) has a vision of creating a platform for building and nurturing academics, technical, innovative and entrepreneurship competencies which are much needed in the development of effective and efficient health care systems in Africa. It is directly

Figure 1.6: UNECA building in Addis Ababa

involved in training, strengthening and expanding programmes of biomedical engineering to different countries in Africa especially those with the greatest need. Figure 1.7 illustrates the expert group meeting of ABEC.

Figure 1.7: Expert Group meeting at UNECA in Addis Ababa

- **CAMTech** has the objective of accelerating medical technology innovation and building of entrepreneurship capacity aimed at improving healthcare delivery to low and middle income countries. It is in this spirit that CAMTech

holds multiple hack-a-thons in different countries like India, Uganda and USA to provide an innovation platform to people living in the developed and developing countries to come up with solutions to problems affecting them. These platforms bring together people from different fields such as business, engineering, social sciences, medicine, among others to brainstorm ideas and develop prototypes of solutions related to health. This consortium also gives grants to award winning ideas to be developed and implemented

- **Amalthea Trust** decided to take a different approach. With most initiatives focusing on donation of equipment, flying out local technicians to teach about one or two devices, Amalthea Trust decided to carry out a comprehensive needs assessment to establish the cause of problems with medical equipment in Uganda and similar countries. They realized that among other reasons, lack of appropriately trained technicians was the major cause of poor equipment conditions. From this assessment, they decided to support the training of technicians at Kyambogo University [Figure 1.8]. They helped to equip the workshops as well as bringing engineers with a wealth of experience to train the local students.

Figure 1.8: Amalthea Trust training at Kyambogo University

- **Engineering World Health** (EWH) is a dynamic global organization serving engineering students, healthcare professionals, communities around the world and, most importantly, patients. EWH inspires, educates and empowers young engineers, scientists and medical professionals from more developed parts of the world to use their engineering skills to improve

global health. EWH offers young professionals an eye-opening, life-changing experience that encourages life-long engagement with global health, and enables them immediately to provide meaningful service to patients in the developing world. EWH also supports training programs in Asia, Africa and Latin America that are building a workforce of in-country biomedical engineering technicians and instructors. Working in partnership with local hospitals, educational institutions and governments, EWH is improving local capacity to run efficient hospitals up to international standards now and in the future.

1.5 Aim of thesis

About the medical devices conditions in Africa have been highlight some different problems among which:

- lack of knowledge about regulation,
- high costs,
- lack of human capital to design and repair medical device,
- and 30% of imported devices out of service.

During the thesis will be evaluate all problems described above and will be proposed possible strategies to want to solve them.

1. **Medical device Regulation**
   Chapter 2, analyze how the medical devices regulation and its harmonization across countries can improve healthcare. Thanks to a work developed with A. Ravizza from Bioindustry park Silvano Fumero in Turin, Italy, and B. R. Bracio with his team work from Anhalt University of Applied Sciences in Koethen, Germany, a paper on the development of an affordable and sustainable system for medical device regulations to provide safe, effective and quality healthcare products for Africa has been written.

2. **Open Source Technologies**
   Chapter 3 analyzes how the Open Source technologies, in particular open source medical device, can improve healthcare in developing country because their low cost. This chapter will describe the expected impacts derived from use of open-source technology and two different cases of study were taken into consideration:

- **the contactless thermometer**, which has been used not only to demonstrate the potential of the Open Source technologies but also as teaching tool in my first experience in Africa, during the Innovator Summer School (ISS) in Addis Ababa, Ethiopia, in 2016. This project consists of a thermometer connected via bluetooth with an Android phone, to read the object temperature. The work was carried out in partnership with Tecno Mobile in Ethiopia;
- **Spectacles 3D printing**, which are manufactured with a totally automatized system, requiring few data from the operator; it is a simple way to answer not only to the high cost of the device but also at the lack of specialized technicians in Africa.

Furthermore Open Source Medical Devices might be an option not only to save costs but also to simplify regulatory process of the design. It is obvious, however that they still need certification to be established on the market.

3. **Capacity building**
   Chapter 4, describes two different teaching experiences and how they can improve the healthcare in Africa.

   - The first training was carried during the Innovator's Summer School (ISS) in Addis Ababa in 2016. My experience during the ISS will be analyzed from two points of view:
     - as student, presenting my prototype of contactless thermometer during the competition,
     - as trainer of BMEs, presenting my prototype as a teaching tool, explaining the use of open resources and their application in African context.
   - My second experience of training has been addressed to Biomedical Engineering Technicians. This type of experience was carried out in partnership with the charity Amalthea Trust based in Malmensbury in UK. I prepared the lessons on the theory of Ultrasound and X-ray and with the help of other two volunteers we trained for 4 weeks at the second class student of Biomedical Engineering Diploma at University of Kyambogo in Kampala, Uganda.

4. **Donation Management**
   Chapter 5, describes how the donated medical device can improve the healthcare in Africa. Thanks to the experience with Amalthea Trust I was able to

visit three different hospitals in Uganda landscape and to evaluate the condition of donated medical equipment.

Questionnaires and interviews to students, technicians, lecturer, physicians and nurses during the ISS and my experience n Uganda were helpful for comparing these approaches as illustrated in Chapter 6.

CHAPTER 2

Status of medical device regulations and their harmonization as solution to improve the healthcare in Africa

Appropriate, affordable and good quality medical devices are indispensable in healthcare services. The majority of countries in Africa do not have a proper regulatory system for medical device for this reason in Chapter 2 evaluates the status of medical device regulation in Africa and describes the necessity of directives harmonization as a first approach to improve the healthcare in Africa.

2.1 Status of medical device regulations

The term *medical device* covers a vast range of equipment, from simple tongue depressor to haemodialysis machines. Like medicines and other health technologies, they are essential for patient care both of rural that specialized hospital [27]. Yet many countries lack access to high-quality devices and equipment that are appropriate for their specific epidemphiological needs. The scene in Figure 2.1 depicts a nurse at Mbale Regional Referral Hospital in Uganda who shows the only, but also broken, endoscope in the hospital. This type of situation is particularly frequent in developing country, where health technology assessments are rare and where only regulatory controls exist to prevent the import or use of substandard devices. With the vast majority of devices in developing countries

being imported, this leaves them prey to unscrupulous market influences and puts patients'lives at risk[27].

Figure 2.1: A nurse at Mbale Regional Referral Hospital in Uganda

Lack of access to quality essential medical devices and health products is just one of the contributing factors to the enormous health challenges that Africa faces. In Africa the agencies rules for medical instrumentations, where these are available, often present a lack of staff for consultation. This is a real problem for people who want to produce, sell, or even donate these devices. This lack, always linked to the missing institutions and political organization, represents a problem for the populations as lots of inadequate and sometimes dangerous devices are put in the Africa markets without quality and safety controls. All these factors make the health system getting worse and very difficult to control and change, causing dramatic break-out of epidemic like the last one of EBOLA, occurring between the end of 2014 and the beginning of 2015 [6].

In this chapter will be analyze the the state-of-the-art for medical device regulations focusing the attention on ABEC countries: Egypt, Ethiopia, Tanzania, Kenya, Uganda, Malawi and Nigeria.

2.2 Will to harmonize

The regulation of Medical Devices across the world varies a lot, ranging from comprehensive to poor. Over the past two decades, the number, range, and complexity of Medical Devices and therefore regulation have increased. In 2001 the World Health Organization (WHO) published "A model regulatory program for Medical Devices" [28].

That was an international guide to assist member states in establishing regulatory programs for Medical Devices. The aim was to provide information to nations without Medical Devices regulatory systems that would enable the production of internationally compatible regulations. In 2003 the WHO published 'Medical Devices regulations. Global overview and guiding principles' [29].

This guideline emphasized the complexity of the Medical Devices industry and identified issues related to regulation. The mentioned document provided guidance to member states wishing to create or modify their regulatory systems for Medical Devices.

2.3 Why harmonise?

Access to new products in Africa can be delayed, sometimes for years, due to complex and costly requirements for regulatory approval in some countries. Costs incurred by the manufacturers will be passed on to customers increasing the price of the goods [30].

- Approval processes in some countries are lengthy and not transparent, leading to costly delays.
- Approval processes vary between countries and manufacturers need to prepare different dossiers for each country, a lengthy and costly process.
- Duplication in facility inspections and clinical trials results in increased cost of goods, making products less affordable.
- Costly and lengthy registration processes are a disincentive to manufacturers to sell in those countries. They are also a deterrent to innovation and the development of new products.
- Setting international standards and streamlining the regulatory process could reduce the regulatory burden, lower costs and remove unnecessary delays to new products reaching patients in Africa.
- The burden on regulators of post market checks on quality could be reduced if networks of laboratories were to adopt common standards and proceedures.

2.3.1 International Standardization Organization (ISO)

The International Standardization Organization (ISO) [Figure 2.2] was set-up in 1946 to facilitate the international coordination and unification of industrial standards. ISO is a network of national standards institutes in 163 countries, and is now the world's largest developer and publisher of voluntary international standards. ISO standards are widely adopted on a regional and national level and support the procedures and practices of Medical Devices development, manufacture, quality control and conformity assessment requirements.

Figure 2.2: ISO logo

2.3.2 Global Harmonization Task Force (GHTF)

The Global Harmonization Task Force (GHTF) [Figure 2.3] was a voluntary group founded in 1993 by the governments and industry representatives of Australia, Canada, Japan, the European Union (EU), and the United States of America [31]. The purpose of the GHTF was to encourage a convergence in standards and regulatory practices related to the safety, performance and quality of medical device. The GHTF also promoted technological innovation and facilitates international trade. The primary means by which its goals were accomplished was via the publication and dissemination of harmonized guidance documents for basic regulatory practices [32].

Figure 2.3: GHTF logo

2.3.3 International Medical Devices Regulators Forum (IMDRF)

The GHTF disbanded in 2012. Its mission has been taken over by International Medical Device Regulators Forum (IMDRF), a successor organization composed

of officials from regulatory agencies, not industry, around the world [33]. The purpose of the IMDRF is to accelerate international medical device regulatory harmonization convergence.

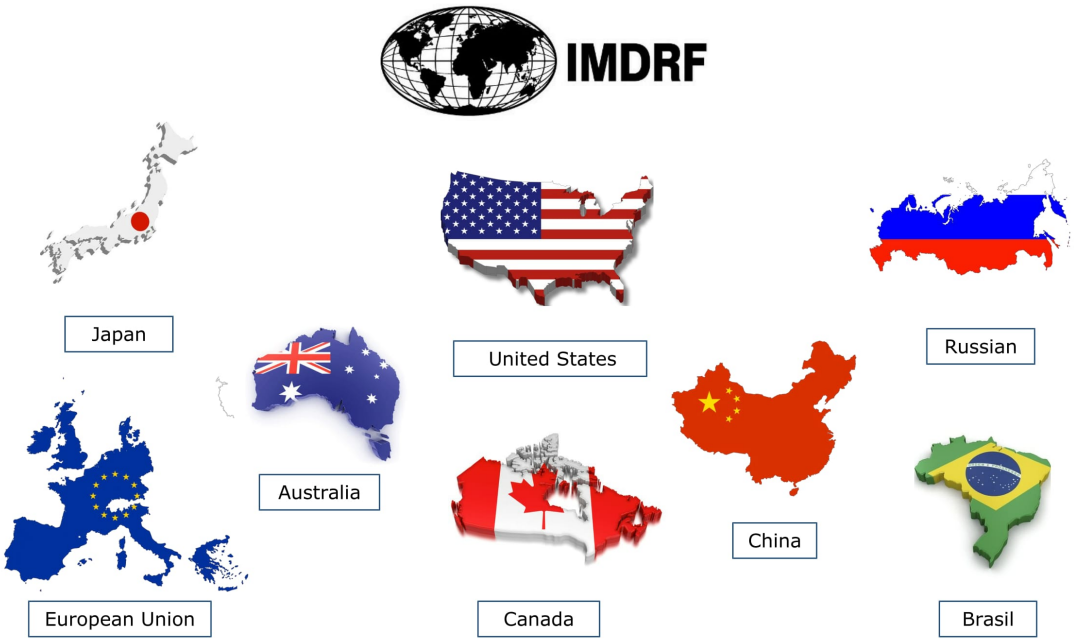

Figure 2.4: IMDRF components

IMDRF was born in October 2011, when representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, EU, Japan and the Unites States [Figure 2.4], as well as World Health Organization met in Ottawa to address the establishment and operation of this new Forum.

Goals of the IMDRF

The goals of IMDRF are to [34]:

- accelerate international Medical Devices regulatory convergence;
- support innovation and timely access to safe and effective Medical Devices globally;
- promote open discussion and the sharing of best practices among regulatory authorities responsible for Medical Devices regulation;

- facilitate frequent exchange of policy and regulatory information of common interest to regulatory authorities;
- provide opportunities to identify commonalities and develop approaches to overcome unnecessary regulatory barriers;
- enhance communication, information sharing and scientific exchange among regulators and a broad range of stakeholders; and
- establish development dialogue with other relevant organizations.

2.3.4 The Global Medical Device Nomenclature (GMDN)

The Global Medical Device Nomenclature (GMDN) [Figure 2.5] is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans [35].

Figure 2.5: GMDN logo

The main purpose of the GMDN is to provide health authorities and regulators, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single generic naming system that will support patient safety [32].

The GMDN is used for:

- Data exchange between manufacturers, regulators and healthcare authorities
- Exchange of post-market vigilance information
- Supporting inventory control in hospitals
- Purchasing and supply chain management.

Medical device experts from around the world (manufacturers, healthcare authorities and regulators) compiled the GMDN, based on the international standard ISO15225 [36]. The work was mandated by the European Commission in

order to provide the necessary tool to carry out the implementation of the Medical Devices Directive, including the European databank for medical devices, Eudamed.

2.3.5 Definition of Medical Devices

The GHTF proposed the following harmonized definition of a Medical Device [12]:

'Medical Devices' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article: intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of Medical Devices, providing information by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

2.3.6 Classification system of medical device

According to GHTF/IMDRF the classification of Medical Devices is the manufacturer's responsibility. The Regulatory Authorities (RA) specifies procedures to be followed by manufacturers during the design, manufacture, and marketing of each Devices. It describes the manner in which a manufacturer should demonstrate conformity to such specified procedures. Classification of a Medical Devices has to be done carefully, because the risk class establishes the correct conformity requirements. An incorrect classification would therefore lead to a conformity assessment procedure, which is not applicable to the particular Devices. GHTF/IMDRF established a Devices classification system consisting of four classes where Class A represents the lowest hazard and Class D the highest. The determination of class should be based on rules derived from the potential of a Medical Devices to cause harm to a patient or user and thereby on its intended use and the technology/ies it utilizes [37], see Table 2.1 [38].

Table 2.2 shows the comparison of different type of classification in the word compared with the GFTH/IMDRF classification.

Table 2.1: Diagrammatic Representation of the Classification System

Class	Medical Devices		In Vitro Diagnostic Medical Device	
	Level	**Device example**	**Level**	**Device example**
A	Low Hazard	Bandages / tongue depressor	Low Individual Risk and Low Public Health Risk	Clinical Chemistry Analyzer, prepared selective culture media
B	Low - moderate Hazard	Hypodermic Needles / Suction equipment	Moderate Individual Risk and/or Low Public Health Risk	Pregnancy self-testing, Anti-Nuclear Antibody, Urine test strips
C	Moderate - high Hazard	Lung ventilator / bone fixation plate	High Individual Risk and/or Moderate Public Health Risk	Blood glucose selftesting, HLA typing, PSA screening, Rubella
D	High Hazard	Heart valves / implantable defibrillator	High Individual Risk and High Public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

Table 2.2: Comparison of classification of Medical Device

GHTF	**United States**	**European Union**	**Australia, Canada, Hong Kong**	**Japan**	**Associate risk**
Class A	Class I	Class I, Is (sterile), Im (measuring)	Class I	Class I Miscellanoous	Low risk
Class B	Class II	Class IIa	Class II	Class II designated and non-designated	Moderate - low risk
Class C	Class II	Class IIb	Class III	Class III	Moderate - high risk
Class D	Class III and unclassified	Class III	Class III	Class IV	High risk

2.3.7 Conformity Assessment Procedure

The conformity assessment is a systematic examination of evidence procedures that may be used by the manufacturer to determine that a Medical Device is safe and its compliance with the Essential Principles (Appendix B) as intended by the manufacturer. Conformity assessment is primarily the responsibility of the Medical Devices manufacturer. However, a review of the process and the conclusions are conducted either by the relevant Regulatory Authority (RA) or a Conformity Assessment Body (CAB). The first one has the power to emanate normative dispositions [39] whereas the accreditation of CAB is the last level of public control in the European conformity assessment system, it is designed to ensure that conformity assessment bodies (e.g. laboratories, inspection or certification bodies) have the technical capacity to perform their duties [40].

1. **Quality Management System (QMS)**
   The manufacturer should implement, document and maintain a QMS that ensures, that the design, manufacturing and supply to the market of the Medical Devices are safe, perform as intended and comply with the relevant requirements. Therefore, when a Medical Devices manufacturer chooses to utilize suppliers, the manufacturer should ensure control over any product or service obtained from such suppliers as defined within the QMS [41].

2. **A system for post-market surveillance**
   The post-marketing surveillance system is part of the QMS and RA or CAB will confirm that such a process is in place, usually at the time of the QMS audit.

3. **Technical documentation**
   Manufacturers of all Devices classes are expected to demonstrate conformity of the Devices to the **Essential Principle of Safety and Performance** (Appendix B) through the preparation and holding of a technical documentation that shows how each Medical Devices was developed, designed and manufactured. The manufacturer creates the Summary Technical Documentation (STED) for demonstrating Conformity to the Essential Principles of Safety. A subject of STED is required to be held at the manufacturers premises for inspection purposes in case of class A or B Devices or to be submitted to the RA or CAB prior to marketing of class C and D Devices. The extent of evidence to be presented depends on the risk class of the device.

4. **A declaration of conformity**
   The Medical Devices manufacturer has to prepare a Declaration of Conformity (DoC) and attest that their Medical Devices fully complies with Essential Principles. This declaration should contain the following information:

   (a) An attestation of compliance with the applicable Essential Principles for Safety and Performance and the applicable requirements of Label and Instructions for Use for Medical Devices,

   (b) Sufficient information to identify the Devices/s to which the DoC applies,

   (c) The Global Medical Devices Nomenclature (GMDN) code for the Devices,

   (d) The risk class of the Medical Device,

(e) The date on which the Declaration of Conformity is issued,

(f) The name and address of the Device manufacturer,

(g) The name, position, and signature of the responsible person who has been authorized to complete the DoC on the manufacturer's behalf.

The RA or CAB may review and confirm the adequacy of the DoC and, if required, examine the supporting documents or other evidence.

5. **The registration of manufacturers and their Medical Devices by the RA** Registration of manufacturers and their Medical Devices by the RA is considered the most basic level of regulatory control of Devices in the market. Prior to placing a Medical Devices on the market, the manufacturer, or distributor, or importer, or authorized representative should provide the RA with the information it needs in respect of registration requirements. The RA will implement and maintain the register.

2.4 European Union Regulation

Until the 1990s, each country in Europe had its own approach to device evaluation [42]. To regulate an uneven and complex market, EU directives that outlined requirements under which a medical device (as well as other commercial goods) could be marketed across all EU member states after earning a Conformité Européenne (CE) mark in any one member country [43]. Since health is the most valuable asset of each individual in life, European regulatory requirements of medical devices are extremely strict and consequently time-consuming. Regulatory processes of medical devices are based on the Medical Device Directive, which consists of three core directives for safety regulations and marketing of medical devices [44]:

- Medical Devices Directive (MDD) 93/42/EEC
- Active Implantable Medical Devices Directive (AMDD) 90/385/EEC
- In Vitro Diagnostic Medical Devices Directive (IVDMDD) 98/79/EC

2.4.1 Classification

The regulatory authorities recognize different classes of medical devices based on their design complexity, their use characteristics, and their potential for harm

if misused [45] [46]. The authorities also recognize that some devices are provided in combination with drugs, and regulation of these combination products takes this factor into consideration.

The guidance for the application of the classification rules for medical devices is set out in Annex IX of Directive 93/42/EEC [46]. There are basically four classes, ranging from low risk to high risk. Table 2.3 shows the classification with relative examples.

Table 2.3: Classification of medical device in Europe

Classification	Example	Risk Level
Class I	Reusable surgical scalpel, stethoscope, bandages, culture media	Low
Class IIa	Contact lenses, epidural catheters, pregnancy test kits, surgical gloves	Low - Medium
Class IIb	Orthopaediac implants, glucose monitors, dental implants, haemodialysis systems, diagnostic ultrasound system	Medium - High
Class III	HIV test kits, pacemakers, angioplastic catheters	High

The classification of a medical device is strongly dependent on its intended use defined by the manufacturer: according to the intended use, time length of use, interaction with the human body and other technical characteristics, the device is considered more or less risky for the patient and therefore classified.

2.4.2 Essential Requirements

Independent of the class of the device, all medical devices must be compliant to the **Essential Requirements** (ERs) on safety, performance and labeling as outlined in Annex I of the MDD, including the requirements regarding the information supplied by the manufacturer, see Table 2.4 [47]. The ERs are the base on which the GHTF defined the Essential Principles in Appendix B. Differently from Essential Principles, the ERs are legislatives.

Essential Requirements (ERs) are the requirements for safety and performance specified in Annex I of the three medical device directives. ERs are divided into Part I (i.e., – general requirements) and Part II (i.e., – requirements for design and construction). Evidence of conformity must be provided for all general requirements in Part I for all devices - regardless of risk classification, design or construction. The Design and construction requirements in Part II may be not

Table 2.4: List of Essential Requirements

No.	Scope
Part I - General Requirments	
1	Risk reduction, acceptable risk/benefit
2	Safety and risk controls
3	Intended performances
4	Lifetime of the device
5	Transportation and storage
6	Side-effects must continue acceptable risk
6a	Clinical evaluation
Part II - Design and Construction Requirements	
7	Chemical, Physical, Biological Properties
8	Infection and Microbial Contamination
9	Construction and Environmental properties
10	Properties for devices with measuring function
11	Protection against radiation
12	Protection against Electrical, Mechanical, Thermal risk, Energy supplies or Energy substances
13	Information supplied by manufacturer

applicable, depending upon your device.

When applying relevant standards to the minimum Essential Requirements for safety (Part I), it was observed that the most common standards are the one for Quality Management (ISO13485), Risk Management (ISO14971), Labeling (ISO15223), Electrical Safety (ISO80601, EN60601-1, EN60601-1-2) and Medical Device Software (EN62304). Depending on the product, there might be device specific standards as well. This leads to the next problem.

When a Notified Body reviews your Technical File or Design Dossier for CE Marking, the auditor must verify that you have addressed each ERs. This is typically demonstrated by providing an ERs Checklist (ERC), see Figure 2.6 as example.

To demonstrate compliance with the ERs, you must provide the following information by filling in the four columns of the ERC:

1. Applicability to your device,

2. Method used to demonstrate conformity with the ER,

Clause	Essential Requirement	Applicable	Method of Conformity	Identity of Specific Documents	Location
General Requirements					
1.	Medical Devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks that may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This will include:	Yes/No	Describe the method of conformity	Identity of conformance documents	Physical location of documents

Figure 2.6: Example of an ERC

3. Reference to the method(s) used, and

4. Reference to the supporting controlled documents.

For all classes, excluding Class I, the manufacturer has to give proof to a Notified Body that their product fulfills these requirements, e.g. by applying relevant standards. A list of harmonized standards is provided by the European Commission. If applicable, the manufacturer then submits the entire product documentation to a Notified Body for certification. In case of a successful certification procedure, some countries also require that the medical device is registered with the local Competent Authority by the manufacturer or an authorized representative.

2.4.3 Guide to CE marking

Description below shows the essential steps to CE marking.

- **Step 1** Classify your products according to Annex IX of Directive 93/42/EEC.
- **Step 2** Decide on your conformity assessment route (Annexes). The following options in Table 2.5 are open to you.
- **Step 3** Appoint an Authorized Representative domiciled in the EEA (EU & EFTA) member states. Register your products if required.
- **Step 4** Follow conformity procedures details in the Directive.
- **Step 5** Proper labeling and affix the CE Marking on the product(s).

Table 2.5: Conformity assessment

Conformity Assessment Procedures	Classes					
Annex	**I**	**I Sterile**	**I Measure**	**IIa**	**IIb**	**III**
II (+ sect. 4)						X
II (- sect. 4)		X	X	X	X	
III					X	X
IV		X	X	X	X	X
V		X	X	X	X	X
VI		X	X	X	X	
VII	X	X	X	X		

2.4.4 Practical example

To better understand the steps that guide to the affixing of CE marking four different practical examples are described, each referring to a different class of device.

- **Class I - Spectacles**
  Spectacle lenses and frames are classified as Class I medical devices. Diagram, in Figure 2.7, shows how the device arrives on the market.
- **Class IIa - Electronic Thermometer**
  Electronic thermometer is classified as Class IIa medical devices. Diagram, in Figure 2.8, shows how the device arrives on the market.
- **Class IIb - Condom**
  Condom is classified as Class IIb medical devices. Diagram, in Figure 2.9, shows how the device arrives on the market.
- **Class III - Pacemaker**
  Pacemaker is classified as Class III medical devices. Diagram, in Figure 2.10, shows how the device arrives on the market.

2.5 What's about the African Medical Device Regulation?

To ensure safety and health in a country, it is essential to have regulations especially in the field of medical products. In 2005, the WHO reported that only 7%

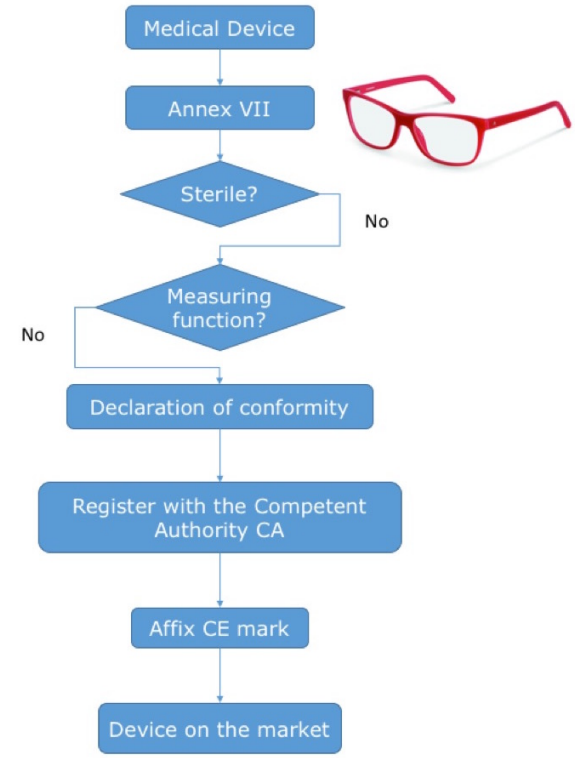

Figure 2.7: Assessment procedure for Class I Medical Device

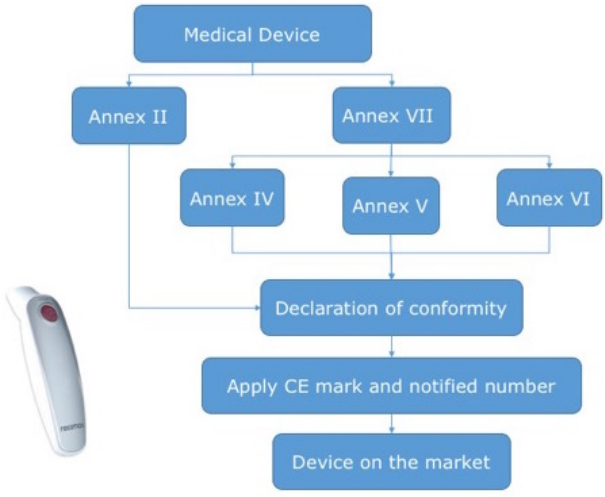

Figure 2.8: Assessment procedure for Class IIa Medical Device

of the 46 sub-Saharan African countries had National Medicines Regulatory Authorities (NMRA) in place. Of the remaining countries, 63% had minimal regulation and 30% had no regulation. A number of international organizations including the African Organization for Standardization (ARSO), The African Network for Drugs and Diagnostic Innovation (ANDI), African Union (AU) and United

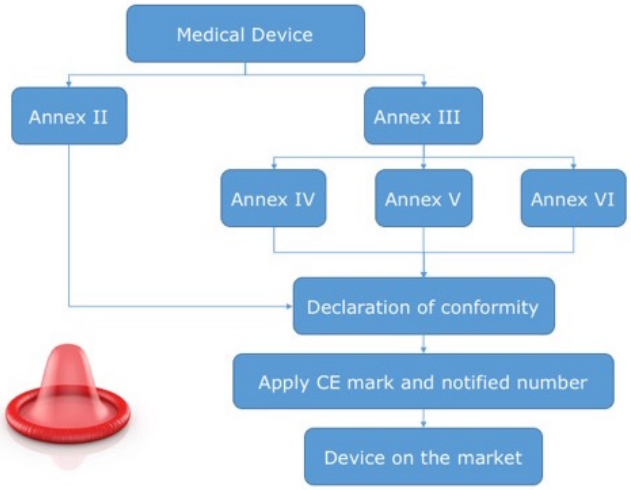

Figure 2.9: Assessment procedure for Class IIb Medical Device

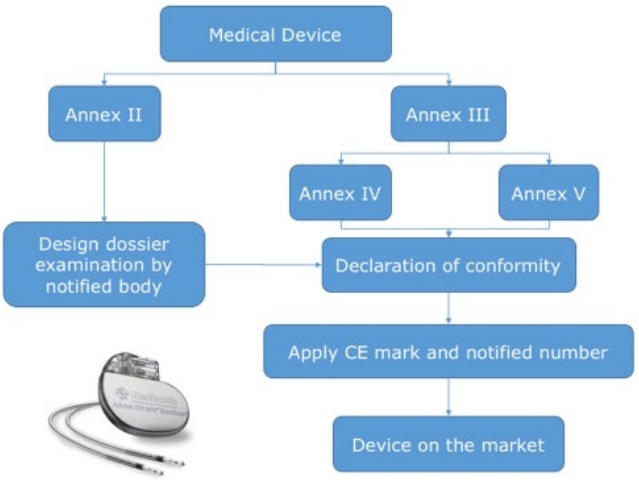

Figure 2.10: Assessment procedure for Class III Medical Device

Nations Economic Commission for Africa (UNECA) have been established to promote harmonization of procedures and standards within the African continent [29] [48].

An example for the importance of regulations is related to donations. If any electrical medical devices were donated by an organization or company, the African countries would have to deal with the issue that they might have a different and/or unstable power supply, which could cause damages to the medical device and even harm the patient or other person. Organizations as WHO, IMDRF and many other institutions are committed to provide improved access to safe, effective and quality healthcare and medical devices to areas where poor or no regulations exist. They make guidelines on regulatory processes freely avail-

able and support countries to implement them in their legislation. Thanks to the international efforts and collaborations with African organizations as well as African governments and physicians, single guidelines and regulations were implemented in some countries [48]. Table 2.6 shows the current state-of-the-art of medical device regulations in ABEC countries, considering the presence of Regulatory Authorities, existence of directives and laws as well as how medical devices are classified.

Table 2.6: Overview on Medical Devices Regulation in ABEC Countries [*not yet ABEC countries; 1 no information]

ABEC Region	National Regulatory Authority	Directive/Laws	Classification of medical devices
Northern Africa			
Egypt	Egyptian Drug Authority (EDA) Medical Device Registration Department	93/42/EEC 2007/47/EC	Class I, Class IIa, Class IIb, Class III
Southern Africa			
South Africa	South African Department of Health (DoH)	No. 101/1965 No. 14/2015 No. 15/1973	Class A, Class B Class C, Class D
Western Africa			
Burkina Faso*	Directorate General of Pharmacy and Drug Laboratories Government (DGPML)	1	1
Ghana*	Food and Drugs Authority (FDA) Ghana Medical Device Department	Act 851	Class I, Class II Class III, Class IV
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)	Cap N1 L.F.N.	Compliance to regulation of the country where it is manufacturer.
Eastern Africa			
Ethiopia	Food, Medicine and HealthCare Administration and Control Authority (FMHACA)	No. 661/2009 No. 9/2012 No. 12/2013	Class I, Class II Class III, Class IV
Kenya	Kenya Pharmacy and Poisons Board (PPB)	93/42/EEC 98/79/EC 90/385/EEC Chapter 244	Class A, Class B Class C, Class D
Malawi	Pharmacy, Medicines and Poisons Board (PMPB)	1	1
Uganda	National Drug Authority (NDA)	1	1
United Republic of Tanzania	Tanzania Food and DrugAuthority (TFDA)	No.1	Class A, Class B Class C, Class D
Zambia	Directorate of Clinical Care and Diagnostic services Medical Equipment Unit	1	1

Nowadays, all ABEC countries have a NRA to regulate and control medical devices. Their names indicate that they are also responsible for food and medicines control. However, medical device regulations require a different approach than those for food or medicines. Table 2.6 clearly proves that African countries orient their regulatory processes on the GHTF system, which can be seen in the four category classification of medical devices. Most of the African countries classify the devices from I to IV Class or A to D Class. Class I or A cover low risk devices and Class IV or D high risk devices that e.g. involve direct contact with the heart, central circulatory and central nervous system. Furthermore, the majority of the ABEC countries implemented or harmonized European directives in their legislation. For example, Egypt implemented the European Medical Device Directive with a European classification of medical products, while Ethiopia and South Africa established their own laws that are harmonized with European regulatory requirements.

The determination of the state-of-the-art with respect to regulation of medical devices in Africa shows that most ABEC members already established a basis for medical device regulations in their countries to ensure safety and quality products. But the majority of those countries still have limited capacities to do so. According to a study performed in 2012 by Simon Peter Rugera [13], those limited capacities might include lack of investments and training to improve and maintain knowledge and skills of personnel. They also found that there is a need to strengthen existing National Regulatory Authorities and for support in specific areas of regulatory processes like development protocols and quality management systems.

2.6 Open Biomedical device as a solution for Africa countries

European Directives for medical device regulations are quite strict and time-consuming but also essential in order to protect the safety and health of each individual. African medical device regulations have an affinity to these European directives. It was observed that all ABEC countries already have a National Regulatory Authority in place, to control and regulate medical devices. The majority of those states also implemented or harmonized directives to medical device regulation, while other countries, which do not have a significant number of regulations, have a huge interest to establish them in their legislation to provide access to safe, effective and quality medical products. However, due to limited

human capacities in Biomedical Engineering, most of the African countries cannot regulate medical devices properly.

In order to enable innovations in Africa, possible alternative has to be explored as Open Source Medical Devices. Open Source Medical Device means to share the design, documentation, source-code, ideas and fixes as well as results and collected data with others. Advantages of the open procedure are its accessibility, sustainability, lower costs and under ideal condition improved safety because everyone can control and check the design dossier [49]. Open Source Medical Device must comply to directives to regulate medical devices in order to protect the safety and health of each individual. They might be an option not only to save costs but also to simplify regulatory process of the design having at least the same safety level. It is obvious, however that they still need certification to be established on the market. So we can provide to simply regulatory process of the design but not the manufacturing one.

CHAPTER 3

Open Source Biomedical Devices to improve the healthcare in Africa

The technology is defined open source when the design is made publicly available so anyone can study it, modify it or distribute it. Some open source projects can potentially be used as medical devices.

The open source approach offers a unique combination of advantages, including reducing cost and faster innovation. Chapter 3 describes how the open source biomedical technologies can be consider as second approach to improve the healthcare in Africa.

Two different projects, manufactured with Open Source technologies, will be described.

1. **Contactless thermometer** in Section 3.5.
2. **Spectacles lenses and frame** in Section 3.6.

3.1 The Open Source Definition

Generally, Open Source Software (OSS) is software that can be freely accessed, used, changed, and shared (in modified or unmodified form) by anyone. Open source software is made by many people, and distributed under licenses that comply with the The Open Source Definition (OSD) in Appendix C [50].

The internationally recognized OSD provides ten criteria that must be met for any software license, and thus the software distributed under that license,

to be labeled "Open Source software". Only software carrying an Open-Source Initiative (OSI) Approved Open Source License, which meets the standards of the OSD should be labeled, "Open Source" software.

The ten criteria that must be met are listed below [51].

1. Free Redistribution
2. Source Code
3. Derived Works
4. Integrity of the Author's Source Code
5. No Discrimination Against Persons or Groups
6. No Discrimination Against Field of Endeavor
7. Distribution of license
8. License Must not be Specific to product
9. License must not Restrict Other Software
10. License must be Technology-Neutral

According with the Open source hardware Association (OSHWA), Open source Hardware is hardware whose design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design. The hardware's source, the design from which it is made, is available in the preferred format for making modifications to it. Ideally, open source hardware uses readily-available components and materials, standard processes, open infrastructure, unrestricted content, and open-source design tools to maximize the ability of individuals to make and use hardware. Open source hardware gives people the freedom to control their technology while sharing knowledge and encouraging commerce through the open exchange of designs [52].

The Open Source Hardware (OSHW) Definition 1.0 in Appendix D is based on the Open Source Definition for Open Source Software.

The distribution terms of Open Source Hardware must comply with the following criteria [53].

1. Documentation
2. Scope

3. Necessary Software
4. Derived Works
5. Free Redistribution
6. Attribution
7. No Discrimination Against Persons or Groups
8. No Discrimination Against Field of Endeavor
9. Distribution of License
10. License Must not be Specific to a Product
11. License must not Restrict Other Hardware or Software
12. License must be Technology-Neutral

Important is noticed that the last five criteria that must be met to be labeled as Open Source Software are equal to the last five criteria about the Open Source Hardware.

3.2 Why "Open" is better than "Closed"?

Open Source and *Closed Source* refer to the way that software and hardware are created and maintained. Open-source software, for example, is like a textbook or patent in that it is available for all to see and improve. Closed-source software is secret, a black box not subject to peer review or independent improvement. The philosophy of open source technology lends itself to making technology available to the masses at relatively low cost compared to proprietary software[54].

Distribution of the code makes it possible for any software developer to change or extend the original product. Hence Open Source is under constant development because anyone in the world can change it. This development approach harnesses the power of distributed peer review and transparency of process. The promise of this approach to software development is better quality, higher reliability, more flexibility, lower cost, and an end to predatory vendor lock-in common with proprietary software[54].

3.2.1 Advantages and disadvantages of Open Source

Before we continue with the exploration of the potential of Open Source for Africa we conclude this section by identify some of the advantages and disadvantages of Open Source listed in Table 3.1 [55].

Table 3.1: Advantages and Disadvantages of Open Source

Advantages of Open Source	Disadvantages of Open Source
Reduced costs and less dependency on imported technology and skills	Available support for OSS
Affordable software for individuals, enterprise and government	Finding the appropriate software
Universal access through mass software rollout without costly licensing implications	Documentation
Access to government data without barrier of proprietary software and data formats	Limited best practices
Ability to customise software to local languages and cultures	Hardware – software fit
Lowered barriers to entry for software businesses	For the same reason, they can be less "user-friendly" and not as easy to use because less attention is paid to developing the user interface.
Supplier independence, limiting vendor lock-in	Although the open source software itself is mostly free, there may still be some indirect costs involved, such as paying for external support
Patches or updates become available quicker, which limits breakdowns and security risks	Although having an open system means that there are many people identifying bugs and fixing them, it also means that malicious users can potentially view it and exploit any vulnerabilities

3.3 Open Source for Biomedical Engineering in African context

There is no question that technology has played a key role in improving the quality and cost effectiveness of health services as well as access to healthcare facilities. Technology is at the heart of effective healthcare services helping medical and paramedical personnel in all stages of their work: from prevention to diagnosis, treatment and monitoring. Yet, technology entails huge investments in economic, physical and human resources.

With healthcare becoming increasingly technology-dependent, from a sophisticated Western teaching hospital to a health post in rural Africa, mismanaged medical equipment has a direct, detrimental effect on the health outcomes of patients. Yet the rapid proliferation of health technologies has greatly outpaced the

development of technology management capacity, placing immense burdens on health systems worldwide [56].

According to the WHO 70-90% of all medical devices donated to the developing world never function as intended, very simple faults, like a broken fuse or dead batteries, account for 15% of these failures. 40% of all donated equipment are not used because there are no manuals available or because of poor user training [19] [21]. These 'poisoned gifts', which are often completely unusable, become a burden on already stretched health systems.

It means that the scarcity of accessible quality healthcare in Africa is inextricably linked not only with the lack of resources, but also with the lack of adequately trained biomedical engineers [57] able to repair medical devices.

While, a couple of years ago, the development of biomedical devices was essentially linked to companies and universities, now several examples of open source biomedical devices have appeared on the web [58], but seldom are they designed to be compliant with safety standards (e.g. the Gammasoft Open electrocardiogram [59]). Although, at present, some of these instruments are not accurate or safe enough to be inserted in the clinical routine, their use can probably save a life more than a damaged, unused (e.g., for high cost) or useless (e.g.,because no one knows how to operate) Magnetic Resonance Imaging machine.

Making the design (software and hardware) available under an open-source license allows anyone to improve and contribute to the device design, leading to very rapid innovation compared to the traditional methods. It also enables the design to be modified for very specific uses, and makes the devices easy to repair, factors which also reduce the impact these devices have on the environment [60].

Indeed, software-reliant devices have also brought on new types of potential risks for patients. Given that medical software (and hardware) is proprietary and patent-protected [61], thus veiled in secrecy there are difficulties in exposing specific problems with these products.

The Open Source approach could, in theory, make it easier to fix, or even avoid, dangerous flaws before they hurt or kill hundreds or thousands of patients.

Today, thanks to crowd-thinking and crowd-sourcing, the design of several products has an intrinsic revision process, driven by a virtual community, composed of a heterogeneous and large population (from highly skilled designers to laymen), which has become an active player, and no longer a passive element. This community is the best analyst in terms of quality, reliability and feasibility.

3.4 Expected impact of Open Source for Biomedical Engineering on the African context

To understand the importance of the Open Source in Biomedical Engineering, different positive impacts that this type of approach has for the developing countries will be evaluated.

3.4.1 Impacts on healthcare

Promoting the open-access, low-cost of medical devices for industries and institutions in Africa as well as in emerging countries in Europe, increases their safety, reliability and finding new solutions for health problems. Thanks to the open innovative technologies is possible to respond to real local issues with safe and efficient devices that will have positive impacts on healthcare.

3.4.2 Impacts on education

Most of African students study abroad and they don't came back in their home country for different reasons like: stability, better working conditions or higher salary. The Open Source technologies can promotes the establishment of network of African Universities engaged in education and high-quality. The open design of biomedical device could encourage upgrading of curricula based on solid engineering principles with courses on new fabrication technologies ad problem solving.

The scene in Figure 3.1 show an Open Source Pulse Oximeter project of a Biomedical Engineering student from Makerere University in Kampala.

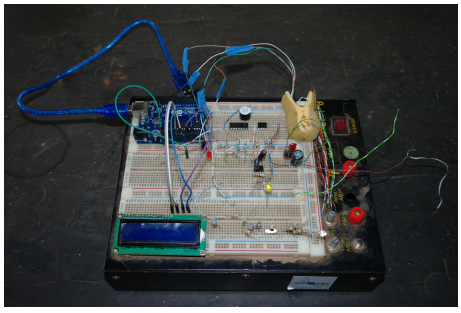

Figure 3.1: Open Source Pulse Oximeter Makerere University's Student

Providing guidelines about safety and regulation on Open Source devices will encourage the growth of a new genre of BME able not only to design innovative

and safe medical devices but also able to chose the most appropriate open-source materials between the choice available.

3.4.3 Impacts in innovation and research

Open projects will create a cooperation between scientist, technologists, clinicians, technicians, regulators and designers who can set up design and research initiatives in the Biomedical Engineering fields.

3.4.4 Impact on harmonization of Medical Devices directives

As discussed in Chapter 2, to ensure safety and health in a country it is necessary having regulations especially for the medical products. Thanks to the international efforts and collaborations with African organizations, as well as African governments and physicians, guidelines and regulations were implemented in some countries. All ABEC countries, as explained in Chapter 2, have a NRA to regulate and control medical devices but furthermore the majority of those countries still haven't capacities to implement correct regulations. For this reason the Open access to the design of the medical devices which has been designed following the EU directives could help to improve the capacities to implement the regulation.

3.4.5 Impact on economic growth and cooperation

As discussed in Chapter 1, the healthcare sector is an indicator of the economic status of the country. The growth of open technologies will contribute to the economic growth both indirectly by providing safe medical devices, which will have a positive impact on healthcare, and directly by playing a role into the medical device market.

3.5 Case of study 1: Contactless thermometer

This section shows an Open Source Contactless Thermometer used as teaching tool during the ISS in Addis Ababa in 2016 where the topic of the school was the mobile health. The contactless thermometer measures the object's temperature with an InfraRed (IR) sensor and it is bluetooth connected with an Android phone through which it is possible to read instantly the object temperature.

3.5.1 Identification of the problem

The temperature of the patient's body is an important vital sign in assessing overall health, typically in combination with blood pressure and pulse rate. Determining whether a patient is afebrile or febrile is an important purpose of a clinical thermometer, since being febrile suggests that the patient is ill. After the long age of mercury thermometer, now banned by a 2009 European directive for safety reasons, it has been replaced from electronic devices that are now the most ordinary way to test temperature almost all over the world. There are two main categories of these, the contact and the contactless technologies. During Ebola epidemic, contactless thermometer received a great success because the thermometer working at distance guarantees hygiene, safety and accuracy [62]. Figure 3.2 illustrates an example of the contactless thermometer application.

Figure 3.2: Application of contactless thermometer during Ebola epidemic

The main advantage of contact thermometer is the possibility to have a precise measurement of the internal temperature, typically through rectal control, generally resulting higher than the superficial of about $0.5°C$ [63] [64]. The real

problem is that some infective diseases can be transmitted through the direct contact, so the testing instruments becomes a dangerous vehicle [65]. These systems are very easy to use, to project and build so that they are generally quite cheap, their efficacy and precision have been confirmed. They usually work with an IR sensor. Pointing this device from a distance of few millimeter (mm) from the skin it is possible to record the temperature in a few seconds. Its use is suggested also for children or people having problems to stay quiet for the time needed by contact thermometer to register the temperature.

3.5.2 The mHealth opportunity for African countries

The abbreviation for mobile health is mHealth, which is a term used for the practice of medicine and public health supported by mobile devices [66]. The term is most commonly used in reference to using mobile communication devices, such as mobile phones or tablet for health services and information. mHealth applications include the use of mobile devices in collecting community and clinical health data, delivery of healthcare information to practitioners, researchers, and patients, real-time monitoring of patient vital signs, and direct provision of care (via mobile telemedicine) [67].

In regions were basic access to healthcare is a challenge, mHealth can provide remarkable opportunities. Sub-Sahara Africa bears the highest disease burden in the world, nonetheless the economic and technological advancements in the region provide opportunities to develop sustainable mobile health solutions to improve health care, see Figure 3.3 [68]. This requires an integrated approach, strategic partnerships and new business models.

Figure 3.3: Example of mHealth in an African Hospital

The recent economic developments across the Africa have been attracting attention from different stakeholders in the mHealth ecosystem. Other mHealth

investment drivers are the increase in mobile access, the development of high quality networks, health care apps and the demand for wearables. Mobile penetration rates in many Sub-Saharan countries are rapidly getting close to exceeding 60% [69] and the population is starting to use mobile phones not only as basic communication tools but also to improve and integrate business and services.

However, to improve healthcare in Africa, the countries should use its positive economic and technological developments should be used. The mHealth ecosystem is a large and complex web of stakeholders that all need to provide their specific input to fully utilize the possibilities of mHealth services.

Integrating mobile technology in current health care strategies provides new ways of healthcare. This facilitates and engages the system, the healthcare professionals and the patients. In developed countries the primary focus is on reducing health care costs, optimizing assets utilization and efficiency, delivering higher quality of care, and improving patient experience. The main focus in Sub-Sahara Africa (and other developing countries) is improving access to basic health care, remote diagnosis, remote monitoring and prevention. Followed by access to health-related information, quality and effectiveness of service delivery, and reducing the shortage of well-educated health care professionals.

3.5.3 The Open Source Contactless Thermometer

Because it is a non contact thermometer the IR thermometer is extremely hygienic and will not spread the infection or illness as it does not come into contact with the skin, so the risk of cross infection is minimised. The idea is to manufacture an IR thermometer through Open Source technologies, furthermore to contribute to the growth in the use of smartphones in medical settings and demonstrate the potential of the mHealth I decided to use the mobile phone to read the temperature.

3.5.4 Standard for Clinical thermometer

The **general** standards for an electro medical device are described in *ISO60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance* [70] whilst the **specific** standards that must be observed when designing a thermometer are mainly described in the *ISO80601-2-56:2009 Medical electrical equipment - Part 2-56: "Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement"* [71].

The purpose of a clinical thermometer is to assess the true temperature of a

reference body site. There are different temperatures at each reference body SITE according to the balance between the production, transfer, and loss of heat. clinical accuracy of a clinical thermometer is verified by comparing its output temperature with that of a reference thermometer, which has a specified uncertainty for measuring true temperature. For an equilibrium clinical thermometer, the clinical accuracy can be sufficiently determined under laboratory conditions that create an equilibrium state between the two thermometers. The intention of this International Standard is to specify the requirements and the test procedures for the verification of the laboratory accuracy for all types of electrical clinical thermometer as well as for the validation of the clinical accuracy of a clinical thermometer that operates in the adjusted mode. Below the most important integration described in ISO80601-2-56:2009 are listed addressing a range of Medical Electrical Equipment (ME equipment) generally known as clinical thermometer.

Scope, object and related standards

As described in clause 201.1 of the ISO80601-2-56:2009, this ME equipment has been widely used to measure patient temperature during monitoring and treatment of disease. Clinical thermometer are designed and fabricated as portable, transit-operable, or hand-held ME equipment for home healthcare and clinical use, or as parts of the stationary me equipment. The requirements and test procedures of this standard have been developed with the intent to make them applicable to a broad range of present and future clinical thermometer technologies, while assuring that every clinical thermometer that conforms to this standard provides an acceptable degree of diagnostic value and acceptable risk.

There are several risks associated with use of this type of me equipment. An obvious risk is a misdiagnosis - for example, a false negative or false positive detection of a fever which leads to a wrong treatment of a patient. Another risk is a possible injury of a patient or operator by the clinical thermometer or its components. Risk control is the main purpose of this standard which describes the requirements and procedures that assure acceptable levels of clinical accuracy and functionality, which should be maintained over the expected service life of the clinical thermometer [71].

Adjusted mode

As described in clause 201.3.201 of the ISO80601-2-56:2009, the output temperature indicated by a clinical thermometer is not necessarily the same as the temperature of the sensor that is thermally coupled to the measuring site. In the

direct mode the output temperature indicated by a clinical thermometer is the same as the temperature of the sensor that is thermally coupled to the measuring site. Often, direct modes are inconvenient. For example, the time response for an accurate measurement might be too slow or it might be impossible to place the sensor close to the desired body site. For some clinical thermometer, the output temperature can be the result of a signal adjustment or conversion and so the mode of operation is called the adjusted mode [71].

Clinical Thermometer

As described in clause 201.3.206 of the ISO80601-2-56:2009, any clinical thermometers contains the essential components illustrated in Figure 3.4

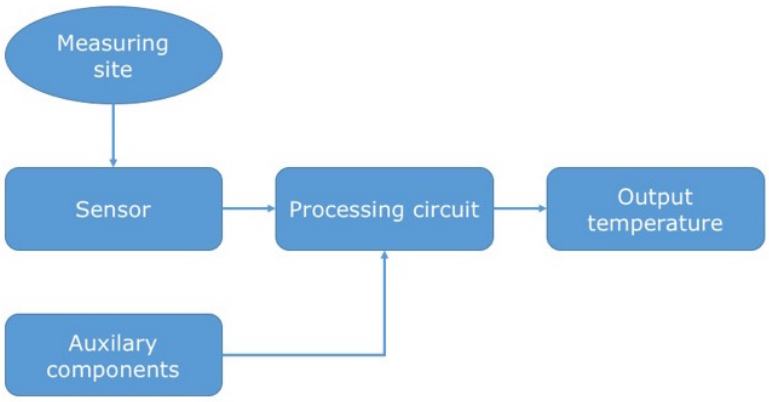

Figure 3.4: General structure of a clinical thermometer

The sensor converts thermal energy into an electrical signal from which an output representation of the temperature is derived. Other auxiliary components and a signal processing circuit can also be included. The auxiliary components and processing circuit include the ambient temperature sensor, optical components, microcontroller, power supply and other components. A microcontroller uses software that processes the signals that are received from the sensor according to an algorithm that displays output temperature in the appropriate format [71].

Reference Body Site

As described in clause 201.3.219 of the ISO 80601-2-56:2009, clinical thermometer measures and indicates temperatures of a specific organ or area of a patient's body called a "body site". The site where the temperature is actually measured

(measuring site) and the site for which the temperature is indicated (reference body site) are not necessarily the same [71].

- The MEASURING SITE is a place on or inside the body of the patient where the PROBE is positioned and to which the SENSOR is thermally coupled.
- The REFERENCE BODY SITE is the part of the body of the patient whose temperature is directly measured or calculated and indicated by the output means of a clinical thermometer.

Intermittent clinical thermometer in adjusted mode: for example, a "pencil" predictive thermometer for which the measuring site and reference body site is not the same e.g. sublingual, rectal, axillary (under armpit); an infrared thermometer for which the measuring site is skin or the ear canal (tympanic membrane); or a contact thermometer for which the measuring site is skin with a different reference body site.

Additional requirements for Essential Performance

As described in clause 201.4.3.101 of the ISO80601-2-56:2009, clinical thermometer span the range from invasive ME equipment with sophisticated alarm system that continually monitors critically ill patients to simple, inexpensive home healthcare environment ME equipment [71].

General test Requirements

As described in clause 201.101.1 of the ISO80601-2-56:2009, an ultimate goal of a clinical thermometer is to assess the true temperature of a reference body site. Table **??** summarizes the types of required testing for certain non-contact clinical thermometer.

The **laboratory accuracy** within the rated output range in normal use shall:

- not be greater than 0.3°C for a continuous clinical thermometer that is not an adjusted mode clinical thermometer, and
- not be greater than 0.2°C otherwise.

While laboratory testing is sufficient for a direct mode clinical thermometer, it is not enough for an adjusted mode clinical thermometer because adjustment algorithms are specific for the anatomical and physiological properties of patients and the environment. These properties cannot be closely simulated by any known laboratory reference temperature source, setting or instrument. Thus, the

clinical accuracy of an adjusted mode clinical thermometer is required to be additionally validated with actual subjects (patients). The clinical accuracy validation shall be conducted in accordance with ISO14155-1:2003 and ISO 14155-2:2003.

To evaluate a **clinical bias**, a sufficiently large number of temperature pairs should be taken by two thermometers - the clinical Thermometer Under Test (TUT) and the Reference Clinical Thermometer (RCT) from multiple subjects with at least one pair of output temperatures per subject. Since three consecutive temperatures are taken from the measuring site by the TUT, only the first one is used in computation of the clinical bias, because in clinical practice typically only one temperature measurement is performed.

Dispersion of output temperature around the clinical bias can be estimated by the standard deviation σ of the temperature differences between the clinical thermometer under test (TUT) and the RCT as measured from multiple subjects. This particular standard defines **limits of agreement** as $2\times\sigma$.

Clinical repeatability (sometimes called the perceived accuracy) is a measure of the consistency of repeated measurements with identical operating conditions when temperatures are taken within short time intervals from the same measuring site of the same subject by the same operator with the same intermittent clinical thermometer[71].

3.5.5 Physical principles of InfraRed light

InfraRed light is an electromagnetic radiation with a large spectrum with a wavelength that ranges between 700nm to 1mm as shown in Figure 3.5.

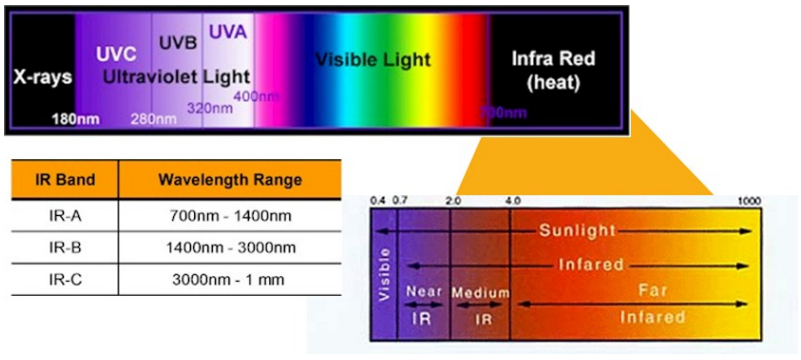

Figure 3.5: InfraRed Spectrum

Every body that is not at the absolute temperature of 0K, corresponding to $-273°$C, releases radiations. The energy of this radiation in proportional to T^4 and it's described by Stefan-Boltzman law [Equation 3.1]:

$$E_n = \sigma \times T^4 \tag{3.1}$$

where σ is the Stefan-Boltzman constant of 5.6710^{-8} $\frac{W}{m^2T^4}$. Human body emits IR radiation into the range 1-15μm, this is principally caused by the flowing of blood in superficial capillaries that are about at 100μm under the skin, which is also the main responsible of thermoregulation through the mechanism of vaso-constriction and vessels dilatation.

The IR radiation emitted by the human body is about $10\frac{mW}{cm^2}$ of superficial epidermis and so for the entire body is 100W. These emissions of energy are largely exploited for diagnostic, as they provide a natural source of information that can be passively detected by the sensors. Thus, these methods are not invasive and reliable at the same time.

Considering all restrictions about the standards, the chosen sensor is the MLX90615SSG-DAG-000-TU-ND by Melexis, Figure 3.6, specific for medical devices.

Figure 3.6: MLX90615 by Melexis

MLX90615 is a passive infrared sensor (PIR sensor); it is an electronic sensor that measures IR light radiating from objects in its field of view [72]. PIR sensors don't detect or measure "heat"; instead they detect the infrared radiation emitted or reflected from an object [72]. The IR sensor, in MLX90615, consists of series connected thermo-couples with cold junctions placed at thick chip substrate and hot junctions, placed over thin membrane. The IR radiation absorbed from the membrane heats (or cools) it. The thermopile output signal is calculated as in Equation 3.2:

$$V_{ir}(T_a, T_o) = A \times (T_o^4 - T_a^4) \tag{3.2}$$

Where T_o is the object temperature absolute (Kelvin) temperature, T_a is the sensor die absolute (Kelvin) temperature, and A is the overall sensitivity. An additional sensor is needed for the chip temperature. After measurement of the output of both sensors, the corresponding ambient and object temperatures can be calculated. These calculations are done by the internal Digital Signal Processor

(DSP), which produces digital outputs, linearly proportional to measured temperatures.

Thanks to its low noise amplifier, 16-bit ADC and powerful DSP unit, a high accuracy and resolution of the thermometer is achieved. The thermometer comes factory calibrated with the digital SMBus compatible interface enabled. Readout resolution is $0.02°C$.

3.5.6 Electric design

Because of limited space, the prototype of the thermometer was made with Arduino MICRO that is one of the smallest boards of Arduino and for this reason easy to integrate. The MICRO is based on the ATmega32U4 microcontroller featuring a built-in USB which makes the Micro recognisable as a mouse or keyboard. Arduino MICRO is shown in Figure 3.7 and 3.8.

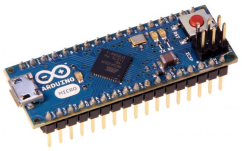

Figure 3.7: Arduino MICRO

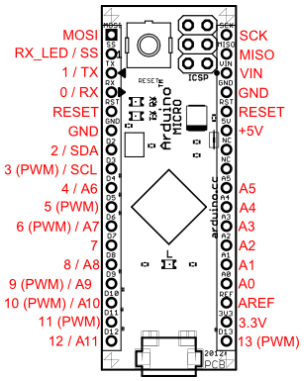

Figure 3.8: Pin mapping MICRO

Figure 3.9 illustrates the electric circuit of the contactless thermometer.

The connection between the sensor MLX90615 and Arduino is realized through the two pins SDA and SCL of I^2C protocol which is a bifilar protocol of serial communication between integrated circuits. The connection between the HC-06 bluetooth module and Arduino is realized through the two pin RX and TX. The HC-06 acts as a serial port through which you can send and receive data, it permits the connection between MICRO and the Android phone. The Arduino's source code is in Appendix E. The circuits works so that when the button is pressed, the LED turns on and a data from the sensor is transfer to the phone through the bluetooth module. A standard 9V battery provides power supply for Arduino that, with a regulator system on board can be powered by a 9V supply, without electric problems. The sensor needs a supply voltage of 3V that is furnished by the Arduino board and the bluetooth module can work at the low voltage between 3.1V-4.2V.

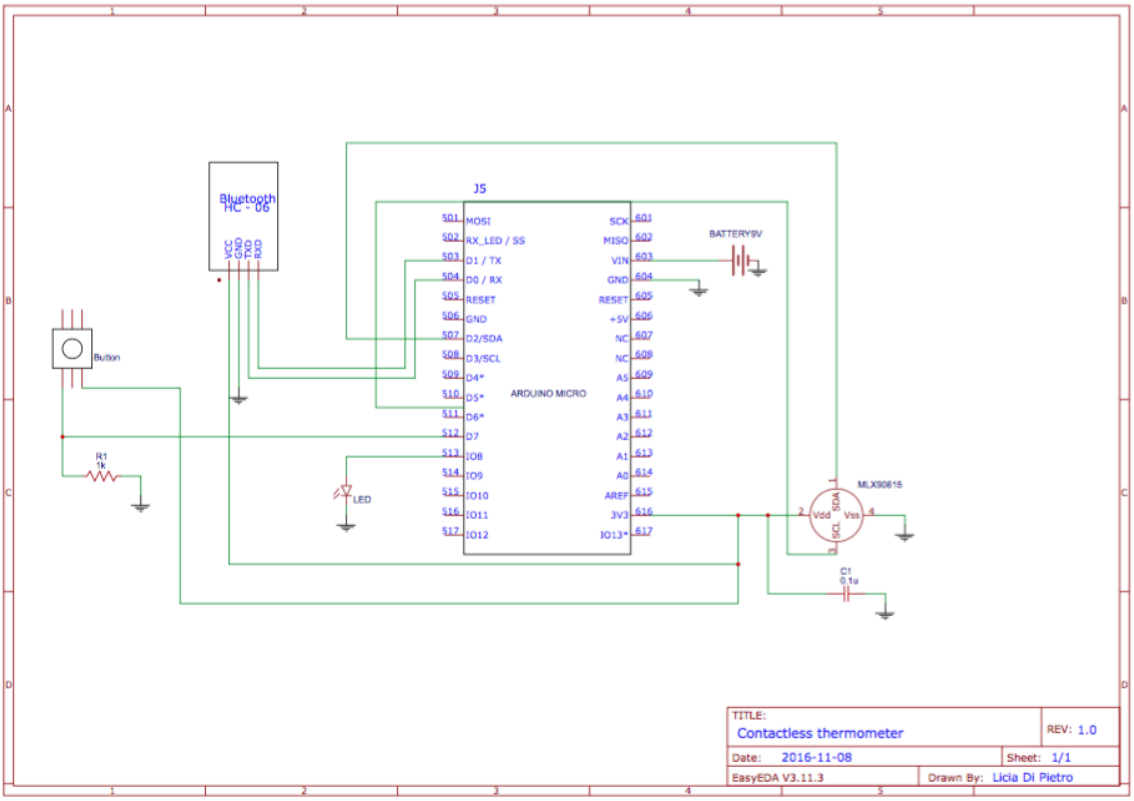

Figure 3.9: Electronic circuit of the contactless thermometer

To understand the utility of the device it is important to evaluate the battery's life. The used battery is a 9V with capacity of 550 mAh. Table 3.2 lists the consumptions of single components of the contactless thermometer.

In Figure 3.10 the diagram shows the maximum consumption during the pairing between Arduino MICRO and an Android phone (Arduino board uses 6 different I/O Pins).

When the thermometer is not paired the consumption is due only at Arduino MICRO and the bluetooth module, as shown in Figure 3.11.

Thank to this analysis it is possible to define the number of reads that can be done with this type of contactless thermometer. Considering that the capacity of the battery is 550 mAh, dividing this capacity for sum of the consumption of all components you get the battery's life, as calculate in Equation 3.3:

$$\frac{550mAh}{232mA} = 2.37h \tag{3.3}$$

Using the device in continuous way the battery life is 2h 22m 12s but considering that the duration of only one read is about 6s, is possible using the thermometer for 1422 times, as calculated in Equation 3.4.

Table 3.2: Component's consumption

Arduino Micro Board	
DC Current per I/O Pin	20 mA
DC Current for 3.3V Pin	50 mA
Sleep Mode	20 mA
MLX90615 InfraRed Sensor	
DC clamp current, SDA pin	10 mA
DC clamp current, SCL pin	10 mA
HC-06 Bluetooth Module	
During the pairing	25 mA
After pairing	8 mA
LED-Basic Led 5mm	
Using current	16-18 mA

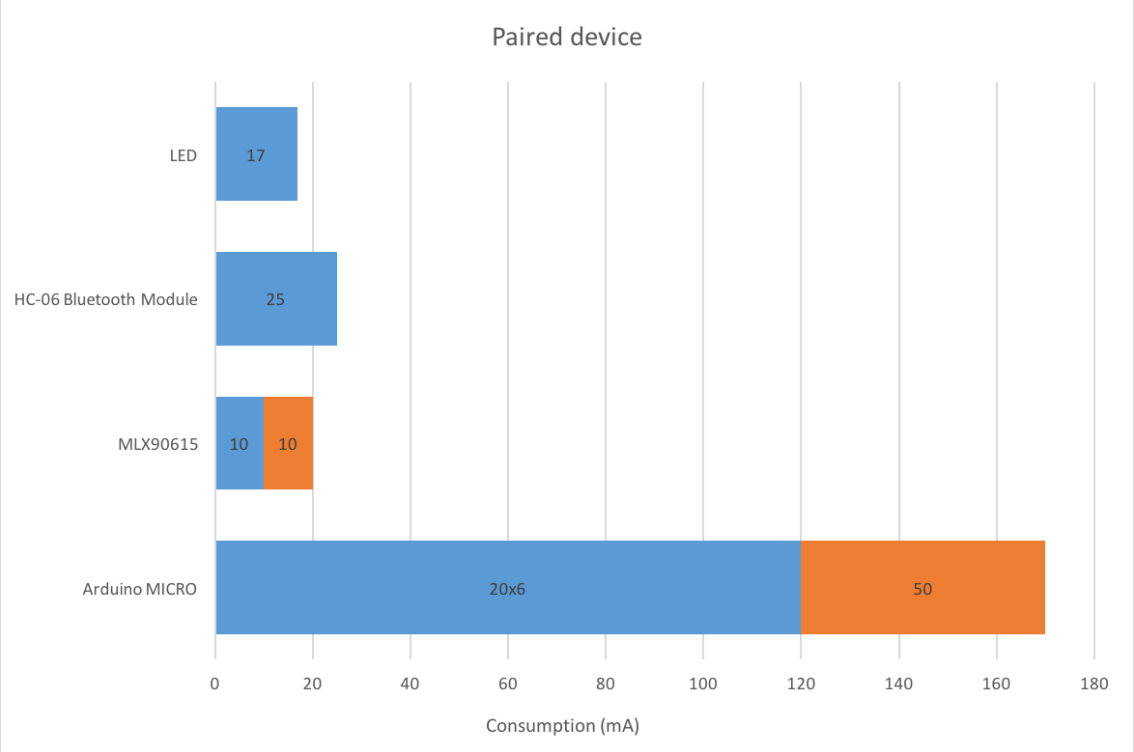

Figure 3.10: Component's consumption diagram for paired device

$$\frac{12s}{6s} + \frac{22 \times 60s}{6s} + \frac{2 \times 60 \times 60s}{6s} = 1422 \tag{3.4}$$

To optimize the battery life it is possible bring some modifications at the cir-

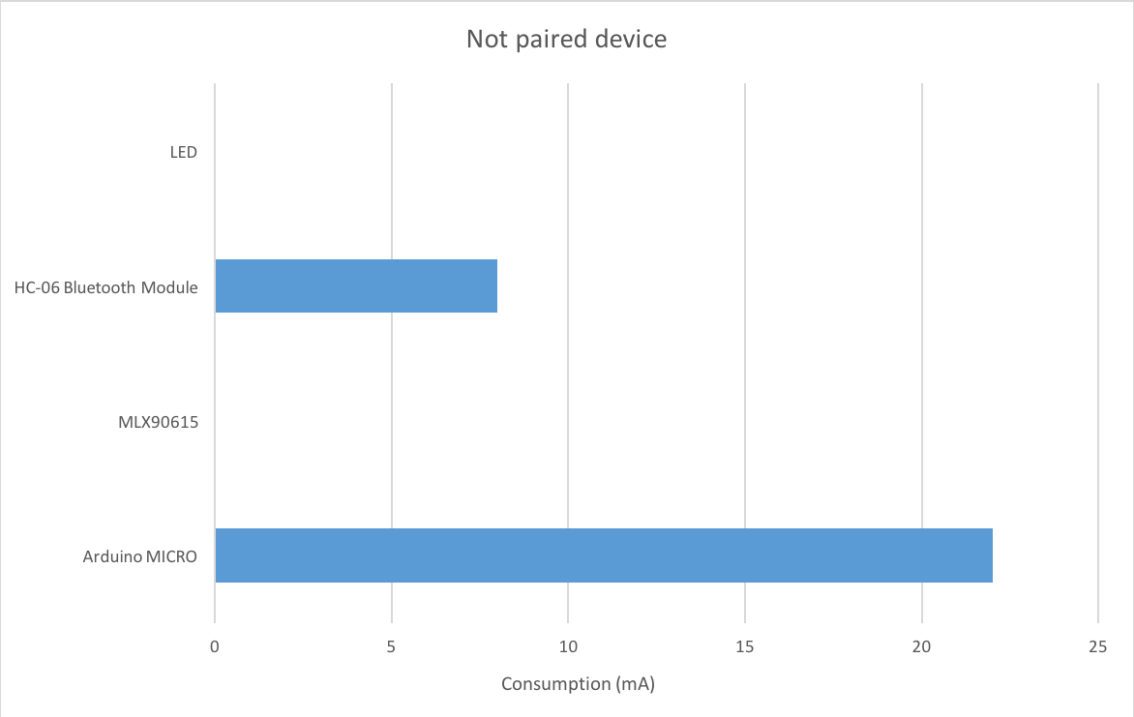

Figure 3.11: Component's consumption diagram for not paired device

cuit: disconnection of Arduino's LED and HC-06's LED. Another way to improve the device's life is using lithium batteries which have more capacity than the alkaline battery. The lithium battery has something like 1200mAh of typical capacity instead 550mAh and in this way it is possible to have the double of reads. To make the device cheaper it is possible to use rechargeable battery, their life is shorter than all others but using them there is a considerable saving of money.

3.5.7 Mechanical design

Concerning the mechanical design of the device, the external case is completely 3D-printed, taking into account the component's dimensions in the internal part:

- 9V battery,
- Arduino MICRO,
- HC-06 module,
- cables.

Appendix G shows the parts of the thermometer case designed with SolidWorks. The sensor is located on the upper part of the case and in the external

part of the thermometer there are the red LED and the button switch.

When the button is pressed, the led turns on, the IR sensor measures the temperature and the HC-06 send the data to the smartphone. Figure 3.12 illustrates the case of the contactless thermometer designed using CAD 3D SolidWorks. The case of thermometer was 3D printed with FDM technology using the Startasys Fortus 250mc and grade ABSplus thermoplastic as Figure 3.13 shows. In particular Figure 3.14 shows the prototype's components where Figure **??** shows the external design of the prototype, instead Figure **??** shows the internal components of the prototype.

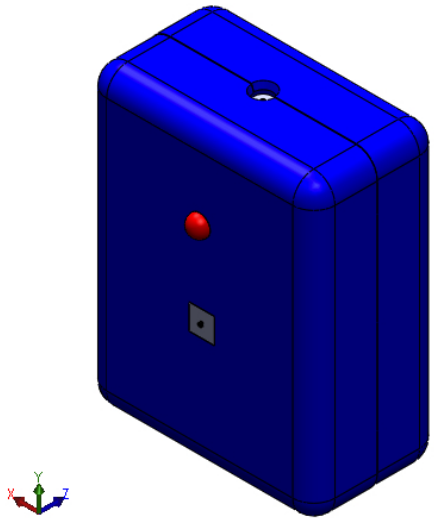

Figure 3.12: 3D design of contactless thermometer

Figure 3.13: Prototype of the contactless thermometer

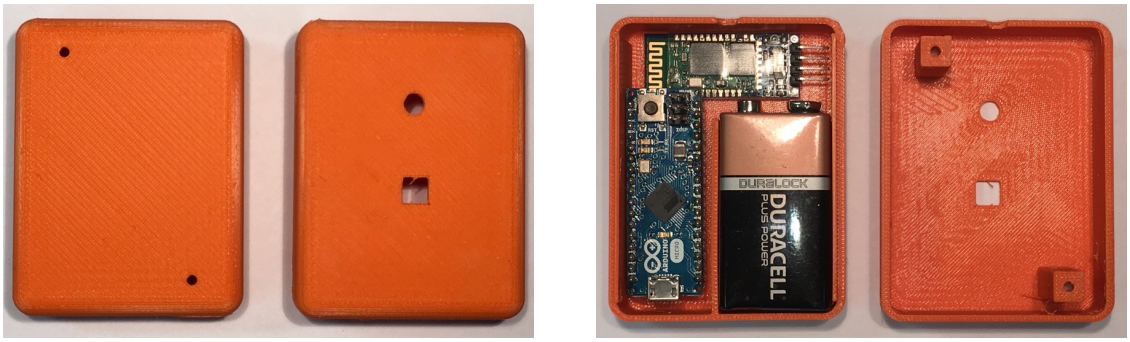

Figure 3.14: Prototype's components

3.5.8 Android Application for contactless thermometer

The mHealth is growing interest in the developing country, as explain in Subsection 3.5.2, for this reason, an Android App has been implemented as a support

for the contactless thermometer. This Android App has been designed in partnership with Tecno Mobile [73] in Ethiopia to show to students during the ISS 2016 the importance of mHealth to improve the healthcare in African and other developing countries. The Android's Application source code is in Appendix F. Through the HC-06 Bluetooth Module Arduino is connected with the smartphone which displays the temperature measures from the MLX90615 sensor. The example of the prototype board is illustrated in Figure 3.15.

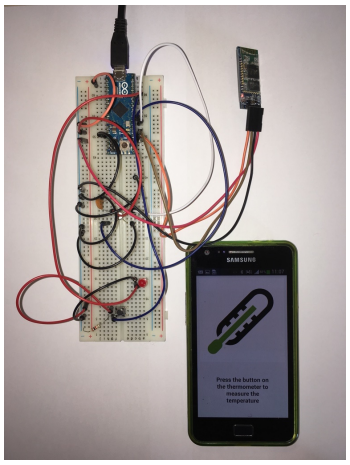

Figure 3.15: Contactless thermometer with the Android App

Figure 3.16 shows the flow diagram used for the design of the Android App and Figure 3.17 shows the interface of the Android App.

3.5.9 Costs analysis of the contactless thermometer

As expected the final product is less expensive than prototype, because mass production lowers costs. In Tables below the costs for all components are described:

- the prototype in Table 3.3,
- the final product in Table 3.4.

3.5.10 Evaluation Parameters of the IR thermometer

To analysis the IR thermometer, the Evaluation Table 3.5 [74] offers a quick sight of the main features of the device. I assigned a score considering my experience on the prototype manufacturing. The motivations of scores are explained in the list below.

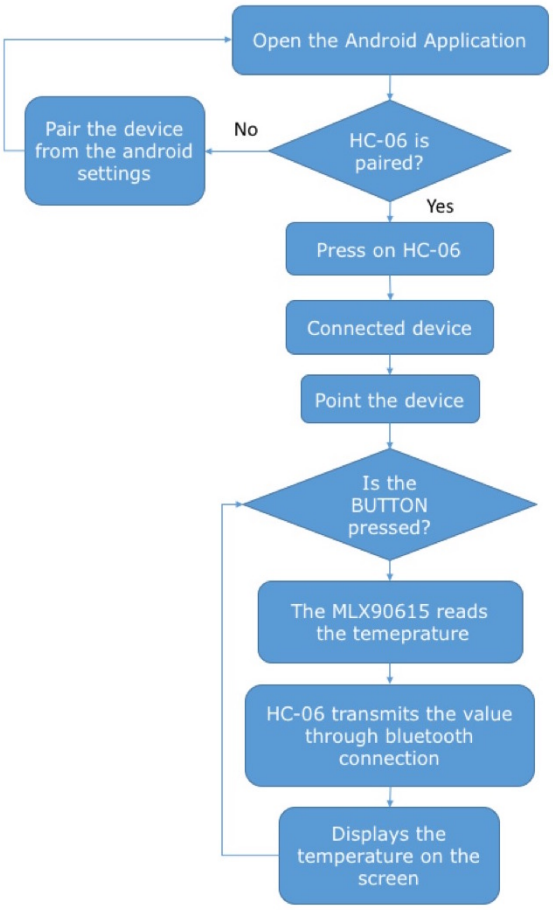

Figure 3.16: Android Application use

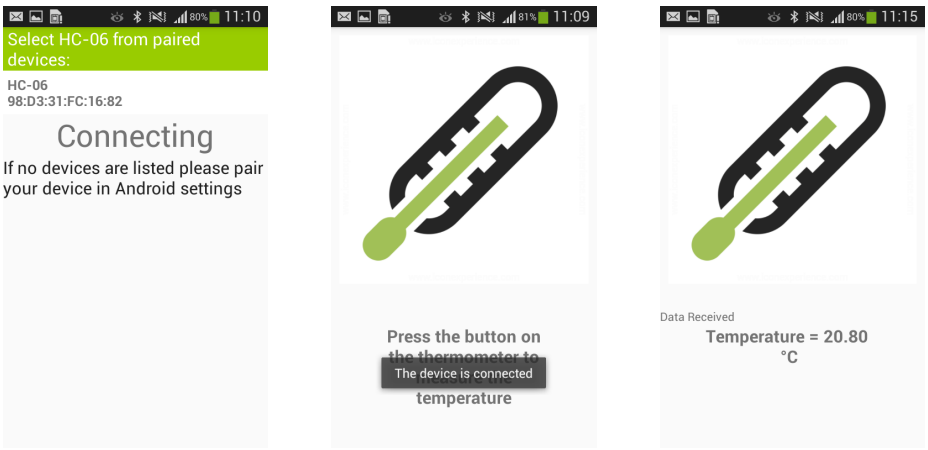

Figure 3.17: Operating Android App

- The cost of the final product of this thermometer is actually very low, comparing to the commercial devices (€40), being less than €15, but it is necessary to underline that the price of the commercial devices considers also the manufacturing and transport prices that in this analysis have not been

Table 3.3: Real costs of the Prototype components

Components	Cost in €
Arduino Micro Board	20
MLX90615	10
Battery 9V	4
3D printed external case	1
Other components	1
Total	36

Table 3.4: Cost estimated of final product components

Components	Cost in €
Microcontroller	4
MLX90615	3
Battery 9V	1
External case	0.5
Printed Circuit Board (PCB)	5
Other components	0.10
Total	14.60

considered.

- Concerning the components and materials availability, a problem can be represented by the sensor. In fact, this is available from some American e-commerce websites delivering all over the world, but customs duties can be relevant and so the time for receiving it.

- The Construction time and the Construction simplicity gained a score of four because the device is very easy to be assembled, but the use of the 3D printer for the external case, takes more time than a traditional industrial method of production. However, having the case a small size, the time is about two hours for all the parts and supports.

- The soundness and the level of precision reachable are very high for the medical parameters requested by the regulations. I used a thermocouple to evaluate the goodness of the IR thermometer. The temeprature was sampled 26 times with both the tools contemporary. Figure 3.18 shows the obtained Bland-Altman plot.

Table 3.5: The evaluation parameters table applied to the IR thermometer

Feasibility	**1**	**2**	**3**	**4**	**5**
Cheapness				x	
Components and material availability					x
Construction time			x		
Construction semplicity				x	
Soundness					x
Level of precision reachable				x	
Adaptability					x
Versatility					x
Usability	**1**	**2**	**3**	**4**	**5**
Level of competence of users					x
Easiness of use					x
Possibility of reuse					x
Management and safety	**1**	**2**	**3**	**4**	**5**
Level of competences of technicians					x
Number of maintenance interventions				x	
Technical check				x	

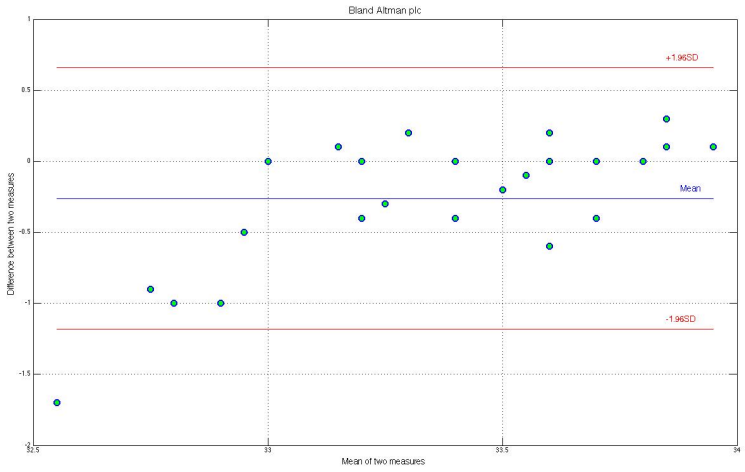

Figure 3.18: Bland-Altman Plot

The Bland-Altman Plot is a scatter plot in which the ordinates shows the difference of two measures and on the abscissa the reference measurement, obtained as the arithmetic mean of the two measurements. The horizontal lines represent the mean of the differences, and the mean difference $\pm 1.96 \times$SD. The mean of the differences allows to estimate if one of the measures either underestimate or overestimate, confronted to the other one, the

actual value; while the other two red lines represent the confidence interval. If the points of the graph are within the two lines it is considered that the two methods provide congruent results, while points outside the two lines are cases in which the two methods are not consistent with each other [75]. Considering the result in Figure 3.18 it is possible to confirm that the two measures are of the same nature.

- Adaptability gained a score of three because, although the sensor is guarantee for well working in a temperature range between $-20°$ and $85°$C, its level of adaptability to different conditions is at normal levels, without representing a particular feature of the device. The same reason concerns the versatility.

- The three parameters relative to usability are all at high levels (score of 5) because the level of competences of users are very low, considering that, once the device is switched on, it is sufficient to point the sensor at the target and press the button to have the measurement. The possibility of reuse is also very high because the device is usable until its damage.

- Finally, also the maintenance and safety parameters gained high score, considering that the number of interventions are very low, because the only problem can be represented by the battery that, being not rechargeable, requires a periodical substitution. The required technical checks are also a negligible number, so the level of competences for these interventions are very low too.

3.6 Case of study 2: Spectacles

The project described in this section gives the possibility to fabricate 3D printable spectacles adherent to a specific patient insofar they are realized with a parametric code that considers the patient's specific data as the total diopter as face width.

3.6.1 Identification of the problem

It is estimated that 2.3 billion people worldwide have refractive error. The vast majority of these could have their sight restored by spectacles, but only 1.8 billion people have access to eye examinations and affordable correction. This leaves approximately 500 million people; Figure 3.19 shows that mostly of them are in developing countries (close to 1/3 are in Africa) and many children, with uncorrected error causing blindness and impaired vision. Many are not aware that there is a cure for their compromised vision, have no one to provide treatment, or cannot afford the appliances they need [76].

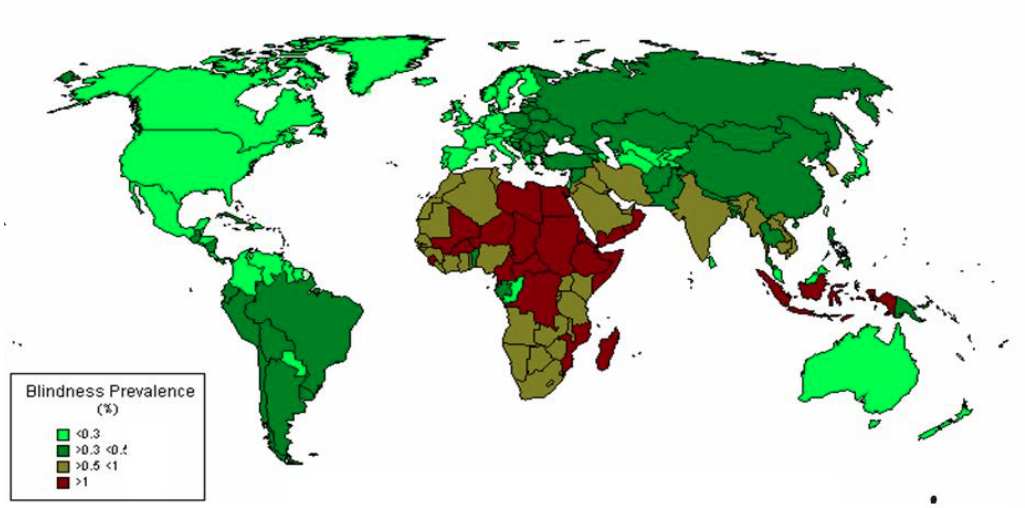

Figure 3.19: Prevalence of blindness(%)

Estimating the global magnitude of blindness and visual impairments is part of the core functions of WHO and since 1995 the Prevention of Blindness team has been issuing regular update of the estimates. In order to set policies and priorities and to evaluated global eye health, it is essential to have up to date information on prevalence and on causes of visual impairment.

Eye care professionals measures vision according to 2 main standards:

- **Vision Clarity** that indicates how grad a person's central visual status is.

Vision Clarity is normally measured using a Snellen chart [Figure 3.20]. It has letters of different sizes that are read, one eye at a time, from a distance of 20 ft (609.6 cm). People with normal vision are able to read the 20 ft line at 20 ft (20/20 vision).

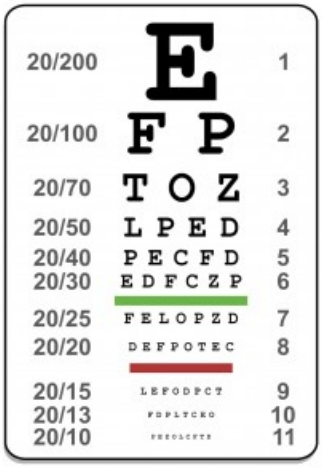

Figure 3.20: Snellen chart

- **Visual field** indicates how a person's entire area of vision range is. Visual Field is normally measured in terms of degrees from the center. People with normal vision are able to to see:
  - $95°$ towards the ear from the center,
  - $60°$ towards the nose from the center,
  - $60°$above from the center,
  - $75°$ below from the center.

The World Health Organization (WHO) defines impaired vision in 5 categories [77]:

1. Low vision 1: is a best corrected visual acuity of 20/70.
2. Low vision 2: starts at 20/200.
3. Blindness 3: is below 20/400 or visual field between $5°$ and $10°$.
4. Blindness 4: is worse than 5/300 or visual field less than $5°$.
5. Blindness 5: is no light perception at all.

The Table 3.6 gives a classification of severity of visual impairment recommended by the resolution of the International Council of Opthalmology (2002) and the Recommendations of the WHO Consultation *Development of Standards for Characterization of Vision Loss and Visual Functioning*.

Table 3.6: Category of visual impairment

Presenting distance visual acuity		
Category	**Worse than:**	**Equal to or better than:**
Mild or no visual impairment 0	20/70	6/18 3/10 (0.3) 20/70
Moderate visual impairment 1	6/18 3/10 (0.3) 20/70	6/60 1/10 (0.1) 20/200
Severe visual impairment 2	6/60 1/10 (0.1) 20/200	3/60 1/20 (0.05) 20/400
Blindness 3	3/60 1/20 (0.05) 20/400	1/60 1/50 (0.02) 5/300 (20/1200)
Blindness 4	1/60 1/50 (0.02) 5/300 (20/1200)	Ligth perception
Blindness 5	No light perception	

Vision impairment has huge social and economic costs to individuals, families, communities and nations. Crucially, 80% of all blindness is preventable or treatable, and programs to tackle avoidable blindness are among the most cost-effective public health interventions available. African experiences a significantly higher burden of blindness and vision impairment than other regions. While Africa has only 11% of the world's population, it is home to approximately 19% of the world's blind population [78].

According to WHO estimates, about 80% of global blindness is avoidable: either it results from the conditions that could have been prevented or controlled if the available knowledge and interventions had been timely applied (e.g. trachoma and river blindness); or it can be successfully treated with the sight restored (e.g. cataract) [Figure 3.21].

In many parts of the world refractive error would become the second largest cause of *treatable* blindness after cataract [79]. Because of the increasing realiza-

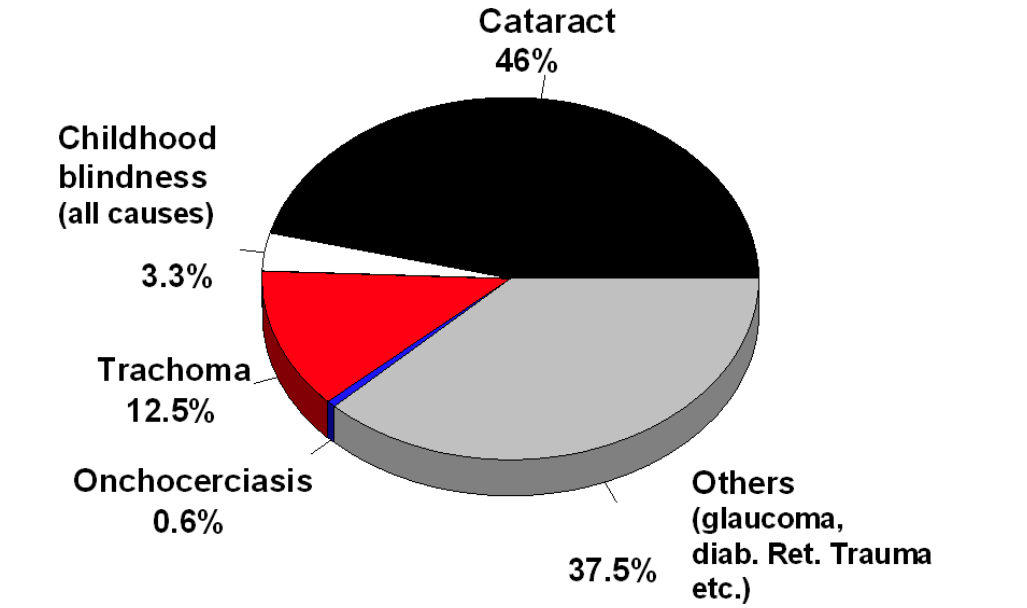

Figure 3.21: Global blindness

tion of the enormous need for correction of the of refractive error worldwide, this condition has been considered one of the priorities of the recently launched global initiative for the elimination of avoidable blindness: VISION 2020-The Right to Sight [80].

VISION 2020 is based on the concept of a broad coalition of all international, nongovernmental and private organizations, which collaborate with WHO in the prevention of blindness and eye care delivery. They share the objective of eliminating avoidable blindness as a public health problem by the year 2020, as shown in Figure 3.22, provided adequate resources are available. These organizations will also jointly work to mitigate the implications of blindness in developmental, social, economic and quality-of-life terms.

Most refractive errors are easily treatable by appropriate refractive correction. However, high refractive error in childhood may lead to amblyopia, resulting in permanent vision loss if it is not corrected during early childhood. Refractive correction can be spectacles, contact lenses, or refractive surgery.

Spectacles are the most commonly used form of refractive correction since they are the most inexpensive and they are the most appropriate treatment for refractive error in developing countries. Provision of spectacles is currently a challenge in many developing countries because of issues related to availability and affordability of reasonable-quality spectacles, with varying degrees of success. These include manufacturing low-cost spectacles in developing countries using trained

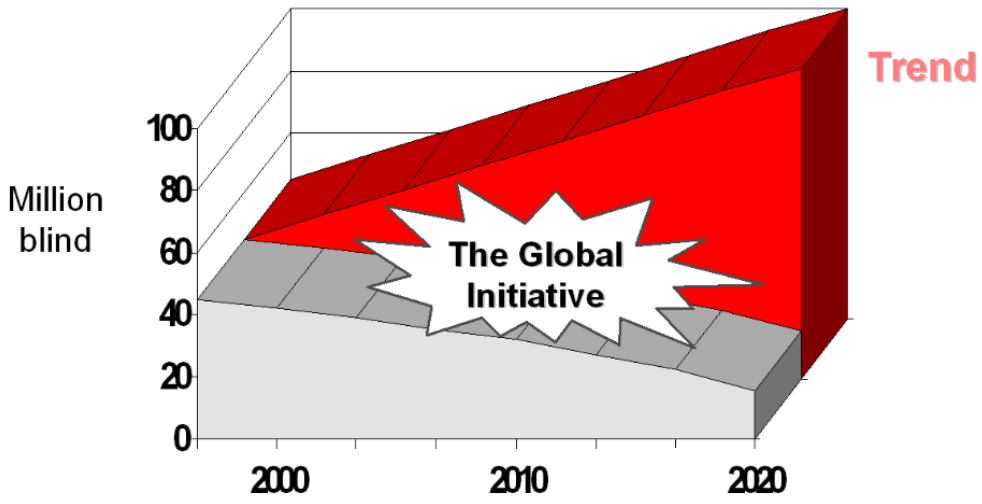

Figure 3.22: The Global Initiative for the Elimination of avoidable Blindness

staff, an approach that has been tried in Africa and Asia [79], use of ready-made spectacles with spherical correction for refractive errors [81], and provision of spectacles at cost price to the poor. Much work still needs to be carried out to optimize the logistic necessary to provide spectacles to all those who would otherwise be blind without them.

Figure 3.23: A man wearing adaptive glasses

Other examples of low cost spectacles are shown in Figure 3.23 where to change the power of lenses, the user turns a wheel on a syringe on the side of the frame to pump more or less silicone oil into a chamber formed by two flexible lens membranes that are protected by a rigid outer lens made of plastic. After the lenses are adjusted for the best vision possible, the user simply tightens the screws on each side of the frame and removes the syringes.

The provision of spectacles in Africa needs that they must be:

1. Easy to fabricate.

2. Accessible to all in terms of costs.

3. Fabricating according to regulation.

3.6.2 Open Source parametric design

About the easiness of fabrication is possible to use a parametric software that through insertion of patient's specific parameters is possible to design a custom made spectacles frame, and in addition considering the total diopter of the patient also graduate lenses can be designed.

Parametric design is a process based on algorithmic thinking that enables the expression of parameters and rules that, together, define, encode and clarify the relationship between design intent and design response [82] [83]. Parametric design is a paradigm in design where the relationship between elements is used to manipulate and inform the design of complex geometries and structures.

The goal is to give the opportunity to anyone, through an Open Source design system, to fabricate tailored spectacles by simply changing a few parameters into a script for taking into account both anatomic dimensions and refractive errors of the patients.

With the parametric code that considers the patient's specific data, also technicians not properly formed can insert few data and obtain a custom made design.

3.6.3 3D printer: an opportunity of access to all

The growth of 3D printing has been rapid in the last decade, with the creation of low cost printers and the availability of easy to use software. The growth and use of this technology is evident across many developed economies. 3D printers are now a common tool for prototyping and used by many design agencies, engineering firms and research institutions. However, there is now a real opportunity to use 3D printing in developing economies and help to leapfrog highly capital intensive manufacturing.

Some predict that this rapid development of 3D printing has started a new industrial revolution which will ultimately influence and affect almost every aspect of life. However, it is already evident that the advantages of 3D printing have opened the way for novel product development and innovations which can provide a range of logistical and technological advantages. The core advantages include [84]:

- Ability for low volume production
- Faster and more responsive production than traditional methods
- Simplification and shortening of manufacturing supply chains
- Democratisation of production
- Ability to optimise and personalise a design

Although developing countries may not be the most obvious place to adopt 3D printing technology, the rapid uptake of mobile phones shows how the use of new technologies can exceed our expectations, considering its use in sub-Saharan Africa now for the 60% of the population[**?**].

The popularity of mobile technology, its ability to increase levels of income, and the rapid adoption demonstrates the real opportunity for 3D printing as the technology development curve is not dissimilar to that of mobile communication. Furthermore, this lack of infrastructure and limited logistics provides a huge opportunity for 3D printers as it could mean rural villages would be able to print their own products and not have to rely on unreliable supply chains. The advancement in mobile communication and the internet continues to support this technology allowing for the rapid transfer of data between sites.

For engineers, this development could enable greater access to these markets through online communities (which are already beginning to form) and enable end users to join the design process, creating more effective [product] solutions to meet their needs.

For all of these reasons 3D printed spectacles could be a solution for the developing countries.

3.6.4 Standards of ophthalmic lens

Standards define the basic requirements that must be met by lenses such as physiological compatibility, flammability, mechanical strength tests and the transmittance of lenses for glasses finished uncut. They are:

- ISO14889:2013
- ISO8980-3:2013

ISO14889 specifies fundamental requirements for uncut finished spectacle lenses, is not applicable to protective spectacle lenses and takes precedence over the corresponding requirements of other standards, if differences exist [85].

Design

As described in clause 4.2 of the ISO14889:2013, spectacle lenses shall be designed so that the overall risk associated with their use according to the reduced to a level consistent with the materials used and compatible with the generally acknowledged [85]

Materials

- ***Physiological compatibility***: as described in clause 4.3.1 of the ISO14889:2013, lenses shall not be made from materials known to be physiologically incompatible or known to create allergic or toxic reactions [85].
- ***Inflammability***: as described in clause 4.3.2 of the ISO14889:2013 when the lens is tested as described in 5.2 of the same ISO there shall be no continued combustion after withdrawal of the test rod [85].

Mechanical strength

As described in clause 4.4 of the ISO14889:2013 uncut spectacle lenses shall withstand the quasi-static loading type test for minimum robustness described in clause 5.3 of the same ISO. The requirement for minimum robustness shall be satisfied if the spectacle lens withstands the the application of a 22 mm diameter steel ball with a force of (100$\pm$2) N. After the test the following defects shall not be apparent:

- ***Lens fracture*** A spectacle lens shall be considered to have fractured if it has cracked through its entire thickness into two or more pieces or if more than 5 mg of the lens material has become detached from the surface [85].
- ***Lens deformation*** A spectacle lens shall be considered to have been deformed if a mark has appeared on the white paper underneath the lens [85].

Transmittance

The transmittance shall conform to the requirements specified in ISO8980-3:2013, 6.1. and 6.2. All tests described in this International Standard are type tests:

- Inflammability, as described in clause 5.2 of the ISO14889:2013;
- Mechanical strength, as described in clause 5.3 of the ISO14889:2013.

Identification

Identification of the spectacle lens to be stated on the package of each individual spectacle lens or in an accompanying document. Information to be made available.

ISO8980-3:2013 specifies requirements for the transmittance properties of uncut finished spectacle lenses and mounted pairs, including attenuation of solar radiation [86].

Classification

As described in clause 5 of the ISO8980-3:2013 spectacle lenses are classified with respect to transmittance as follows [86]:

- clear spectacle lenses, having no intended colour (including grey) in transmission;
- uniformly tinted spectacle lenses;
- gradient-tinted spectacle lenses;
- photochromic spectacle lenses;
- polarizing spectacle lenses

Requirements

As described in clause 6.1 of the ISO8980-3:2013 the fundamental requirements for uncut finished lenses are in ISO14889 [86].

Test Methods

Clause 7.1 of the ISO8980-3:2013 specifies reference methods for transmittance properties of spectacle lenses. For purposes of quality control, etc., alternative test methods may be used if shown to be equivalent [86].

3.6.5 The prototype of 3D spectacles

The used method to fabricate the prototype of the spectacles in the following subsections will be described.

- Subsection 3.6.6 describes the Physical principle of ophthalmic lenses. It is important underlined that in this study only spherical lenses used to correct myopia and hyperopia were considered.
- Subsection 3.6.7 descries the choice of the software used to implement the parametric code to design the spectacles.
- Subsection 3.6.8 describes the choice of the stereolithography as a 3D printer thanks to its high resolution to print te lenses.
- Subsection 3.6.9, summarizes the positive and negative aspects of the prototype.

3.6.6 Physical principles of ophthalmic lenses

The eye is a sense organ complex, derived by evolution from the light-sensitive spots on the surface of the body of invertebrates; it is responsible for vision. Some anatomical considerations about the eye structure, optic analysis, image formation, and defects of image formation will be made before the treatment from the optical point of view.

Eye structure

The main structures of the eye are shown in Figure 3.24 The **sclera** is the outer protective layer of the eyeball, as amended in the front to form the transparent **cornea** from which the light rays entering the eye. Inside the sclera is the **choroid** which contains many blood vessels that nourish the globe structures. The latter two thirds of the choroid form the **retinal**, nerve tissue containing the receptor cells. The **crystalline lens** is a transparent lens held in place by a circular ligament of said crystalline connected to the ciliary body, the thickened edge of the choroid, containing circular and longitudinal muscle fibers. In front of the lens there is the **iris**, an opaque structure that delimits the pupil and pigmented. The iris contains circular muscle fibers that constrict the pupil and radial muscle fibers that dilate allowing it to vary the amount of incoming light up to 5 times.

The space between the lens and the retina is filled with a colorless gelatinous substance, the **vitreous humor**. The **aqueous humor** is a transparent substance that fills the anterior chamber with the function to nourish the cornea and lens [87].

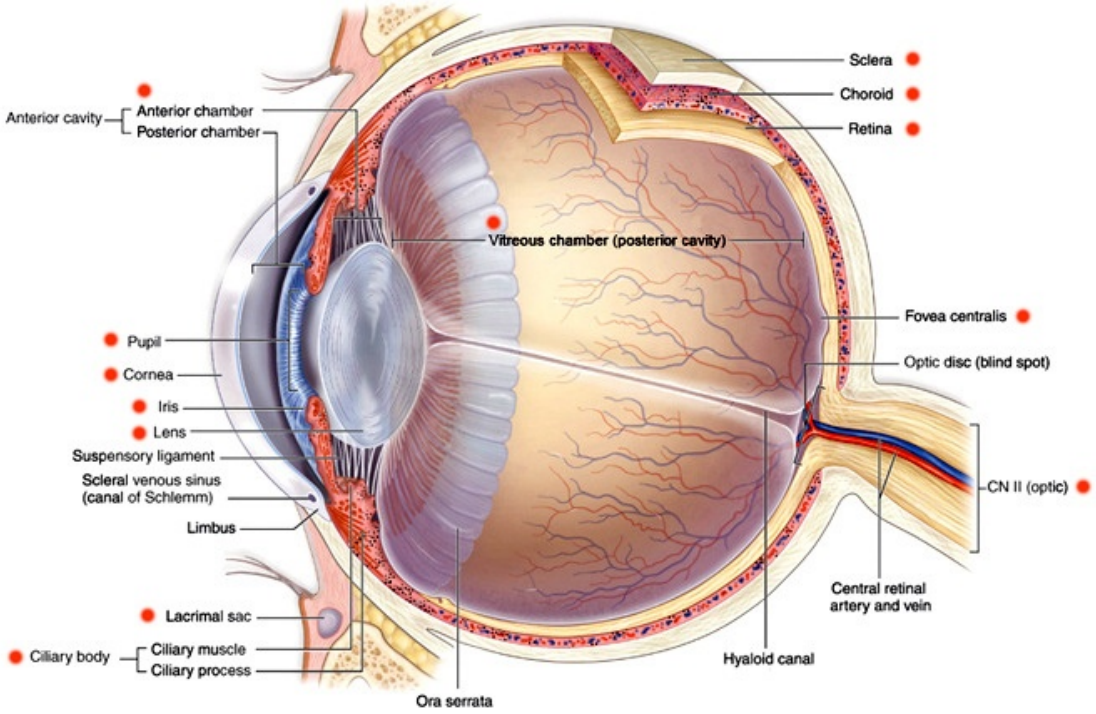

Figure 3.24: This diagram lists many of the essential components of the eye's optical system

The **retina** [Figure 3.25] is the third and inner coat of the eye which is a light-sensitive layer of tissue. The optics of the eye create an image of the visual world on the retina (through the cornea and lens), which serves much the same function as the film in a camera. Light striking the retina initiates a cascade of chemical and electrical events that ultimately trigger nerve impulses. These are sent to various visual centers of the brain through the fibres of the optic nerve. Neural retina typically refers to three layers of neural cells (photo receptor cells, bipolar cells, and ganglion cells) within the retina, while the entire retina refers to these three layers plus a layer of pigmented epithelial cells [87].

Rods [Figure 3.25] are about 120 million per eye: they are very sensitive to light and are the receptors for night vision. The **cones** [Figure 3.25] are about 6 million per eye: have much greater visual acuity, are responsible for the intense light and vision of that color. In fact there are 3 different types of cones, each containing a photopigment with maximum sensitivity at wavelengths of 440nm (blue), 535nm (green), 665nm (red). Throughout the retina, the number of rods

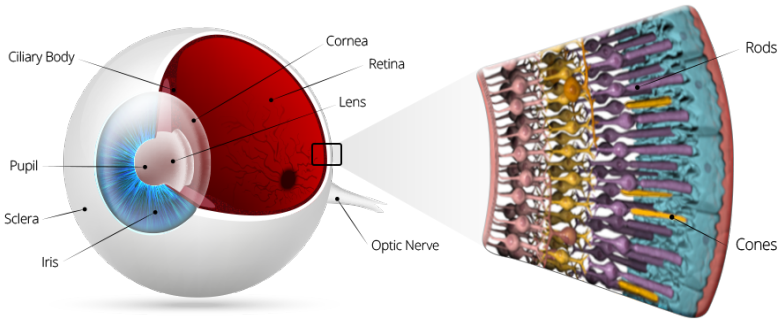

Figure 3.25: Focusing on retina

prevails on one of the cones except that in the fovea. The spectrum range to which the eye is sensitive varies from 390nm to 780nm.

Optics analysis and image formation

In Tables 3.7 and 3.8 some of relevant optic data [88] are listed. The complex of ocular diopter can be thought of as a lens system with a front focal length of 16.2 mm in front of the eye, a back focal length of 24 mm on the retina. The diopter defined as the reciprocal of the focal distance in meters [m^{-1}], a normal eye at rest has +61.478 diopters and then f=16.2 mm.

Table 3.7: Refractive index

Air	1.000294
Lachrymal film	1.34
Cornea	1.376
Aqueous and Vitreous	1.336
Lens	1.4085
Total	1.479

Table 3.8: Characteristic of ocular diopter

Dioptric Power	61.478 D
First focal distance	16.2 mm
Second focal distance	24 mm

In order for an object to be focused its image must fall on the retina. In a normal eye (*emmetropic*), when the ciliary muscle is released and the ligaments are stretched, a place object at infinity, which in practice means place over 6 m, is focused on the retina: when this happens it is said that the ' object is located on the far point. If the object is located within 6 m her picture would fall behind the retina and would therefore not boulder fire. Thus, the ciliary muscle contracts, the ligaments are released and the lens assumes a more convex shape, thus

increasing its refractive power and allowing the focusing on the subject. This process is called accommodation. There is a limit to the increase of the curvature and therefore the light rays coming from objects close can not be brought into focus: the closest point which can be focused by means of accommodation is called the near point of vision and on average is 25 cm from the eye (7 cm for a young up to 100 cm for a senior).

Defects of the imaging formation

The most common refractive disorders are: presbyopia, myopia, hyperopia and astigmatism.

- **Presbyopia** [Figure 3.26] is the reduced ability to focus on near objects. The elasticity of the crystalline lens allows the lens to change curvature (accommodate) to focus clearly on near objects. From the mid to early 40's the crystalline lens hardens due to a natural aging process resulting in the diminished ability to accommodate making tasks such as reading and using your smartphone or computer very difficult. Patients often complain about eyestrain, difficulty in reading fine print unless there is increased illumination and their arms being too short to read at a clear comfortable distance. Presbyopia can be treated with spectacles, contact lenses and refractive surgery [89].

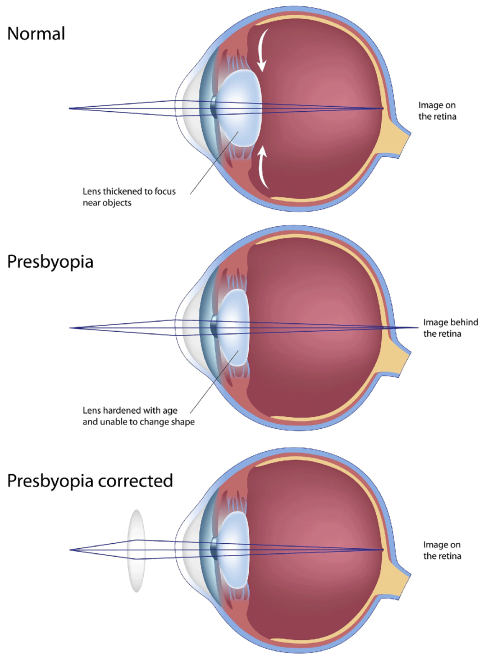

Figure 3.26: Normal vision and presbyopia

- **Myopia** [Figure 3.27] is more commonly known as short sightedness, whereby patients have difficulty focusing on distant objects. Light entering the unaccommodating eye focuses in front of the retina causing the image to be blurred. Myopic patients often complain about reduced distance vision. Near vision may also be diminished depending on the amount of myopia. Myopia can be treated with spectacles, contact lenses and refractive surgery. [90]

- **Hyperopia** [Figure 3.27] is more commonly known as far sightedness. Light entering the unaccommodating eye focuses behind the retina.Depending on the amount of hyperopia patients may be asymptomatic or complain of eyestrain, headaches and fatigue more especially when performing near tasks. Hyperopia can be treated with spectacles, contact lenses and refractive surgery.

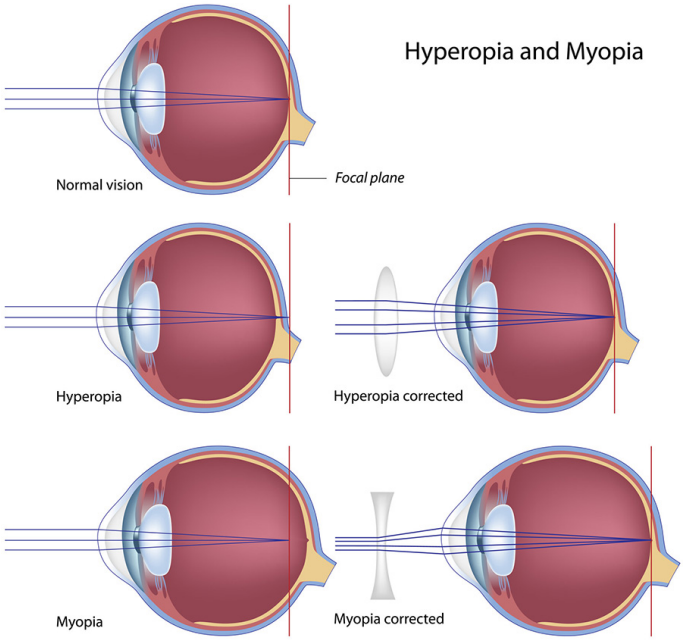

Figure 3.27: Normal vision, myopia and hyperopia

- **Astigmatism** [Figure 3.28]occurs when the shape of the cornea is more oval as opposed to round, which can cause both distant and near objects to be blurred relative to the amount of astigmatism. Patients are often told by optometrists that their eyeball is rugby shaped. A sharp, clear image is unable to be focused on the retina due to variations in the different meridians in the eye.There are two types of astigmatism namely, regular and irregular astigmatism. Regular astigmatism occurs when the two principal meridians

of the cornea are uniform and are at right angles to each other, one meridian having the greatest curvature to the other. Irregular astigmatism occurs when the two principal meridians are not at right angles to each other nor is the curvature uniform. Astigmatism can be corrected through spectacles, contact lenses and refractive surgery.

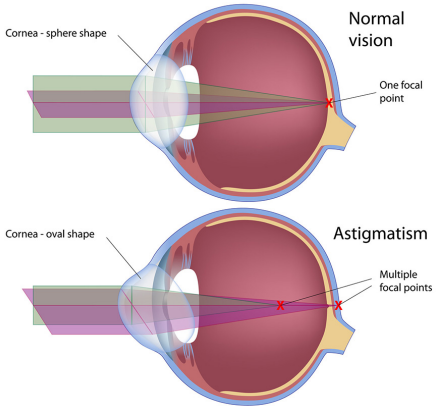

Figure 3.28: Normal vision and astigmatism

Ophthalmic lenses

Ophthalmic lenses bend light to correct focusing defects of the eye. Lenses that are thicker in the middle and thinner at their edge converge light and can be used to correct hyperopia. Lenses that are thinner in the middle and thicker at their edge diverge light and can be used to correct myopia. Lenses that correct astigmatism have a non-rotationally symmetric surface with unequal curvatures in different meridians. We consider only spherical lenses used to correct myopia and hyperopia.

Spherical lenses are typically simple, consisting of only two surface. Each area has its refractive power and it is defined as:

$$D = \frac{n' - n}{r} \tag{3.5}$$

Where n′ is the refractive index where light is entering and n is the refractive index of the medium from where the light is coming out; r is the curvature radius, D is diopter. Assuming you have a lens immersed in the air (n=1):

$$D_1 = \frac{n - 1}{r_1} \tag{3.6}$$

$$D_2 = \frac{1 - n}{r_2} \tag{3.7}$$

To get the total dioptric power of the lens you have to make the sum:

$$D_{tot} = D_1 + D_2 \tag{3.8}$$

If you want a lens with a dioptric power D=+8.00DS (spheric diopters) you can get it in different ways:

$D_1 = +4.00DS$	$D_2 = +4.00DS$	$D_{tot} = D_1 + D_2 = +8.00DS$	equi convex
$D_1 = +6.00DS$	$D_2 = +2.00DS$	$D_{tot} = D_1 + D_2 = +8.00DS$	biconvex
$D_1 = +8.00DS$	$D_2 = 0DS$	$D_{tot} = D_1 + D_2 = +8.00DS$	plane convex
$D_1 = +10.00DS$	$D_2 = -2.00DS$	$D_{tot} = D_1 + D_2 = +8.00DS$	meniscus

The surface with lower dioptric power (in module) is defined as *base curve*.

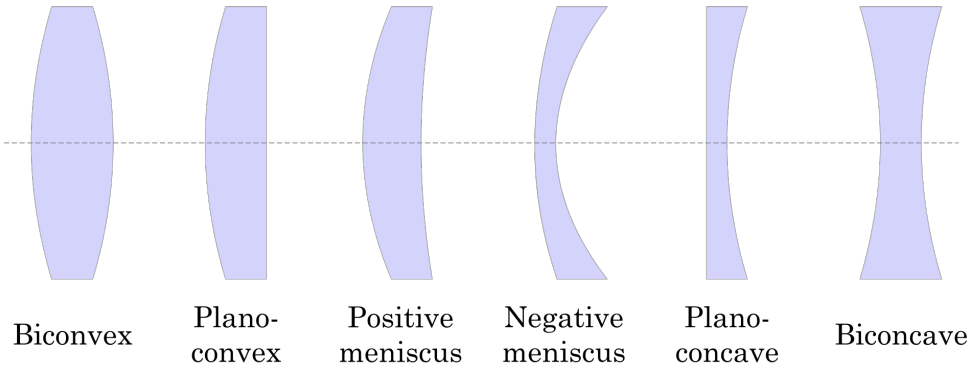

Figure 3.29: Categories of Lens Form

The combination that minimizes the aberrations, that are deviations from a perfect mathematical model, is called *best form* and usually consists of a meniscus, Figure 3.29 for this reason all of our studies are focused on *meniscus lenses*, negative and positive, used to correct receptively myopia (whit negative meniscus lenses) and hyperopia (with positive meniscus lenses).

3.6.7 OpenSCAD parametric design

The script based OpenSCAD software [Figure 3.30] was used for 3D modeling the spectacles, in particular Figure 3.31 shows the frame design and Figure 3.32 the design of graduated lenses.

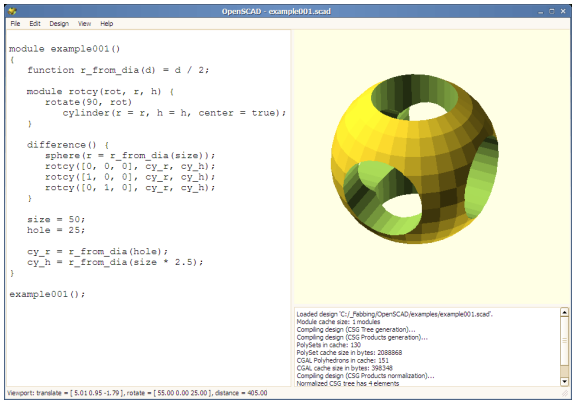

Figure 3.30: OpenSCAD interface

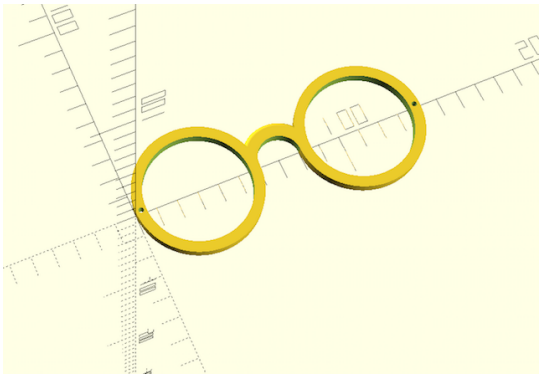

Figure 3.31: Frame spectacles designed with OpenSCAD

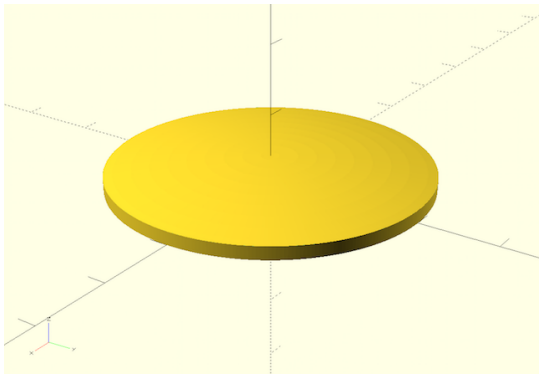

Figure 3.32: Positive Meniscus lens designed wit OpenSCAD

The OpenSCAD codes in Appendix H and Appendix I show respectively the code to design the spectacles frame and graduated lenses. To fabricate a good quality lenses is necessary define the maximum resolution of the design in the OpenSCAD script. Lenses with different resolutions were evaluated ($fn is the symbol that OpensSCAD use to define the resolution):

- $fn=100 - low resolution,
- $fn=1000 - high resolution.

With it is possible set the resolution also higher than 1000 but high resolutions have effects on the rendering time. For example to make the .STL (STereo Lithography interface format) file of the lens with $fn=100 less of 1 minute is necessary whereas with $fn=1000 around 4 hours are necessary. With $fn=100 the design appeared with separate concentric circle on the surface whereas with $fn=1000 the design was good because the distance between the concentric circles is reduce to the minimum and for this reason I decided to not increase further the resolution.

The OpenSCAD script in Appendix H needs the patient' dimensions as the face width and the temple measure to design the spectacles frame instead the OpenSCAD script in Appendix I needs the total dioptric power of lens, negative for myopic patient or positive for hyperopic patient, to design graduated meniscus lenses.

3.6.8 3D printed Spectacles

The objective for this project was to find easy, an easy and inexpensive to produce quality lenses, possibly making use of 3D printer technology. The layer-by-layer approach of all 3D printers technologies available on the market makes this target challenging due to the stair stapping affect that limit the optical transparency.

The spectacles frame was 3D printed with Fused deposition modeling (FDM) technology using the Stratasys Fortus 250mc and grade ABSplus thermoplastic [Figure 3.33].

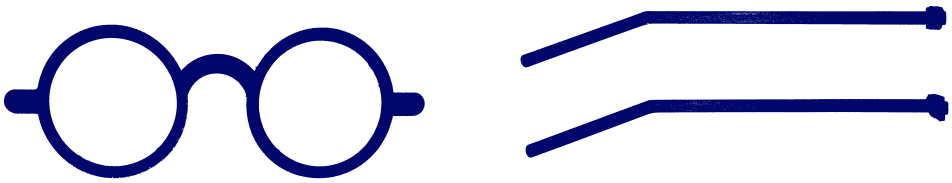

Figure 3.33: 3D printed Frame

Most 3D printers start with a solid plastic and apply it in layers in a heated chamber that allows the plastic layers to stick to each other. The thickness of these layers determines how finely the printer can render detail in the printed objects. Differently from the FDM technologies the advantage of the stereolithography is using a liquid material that solidifies when light is applied. Some of these printers use ultraviolet light while others use lasers. The use of a liquid material allows for the printing of much more detailed and smooth objects such as lenses. The ability to simply print out a lens without intermediate steps would be enormously useful in bringing down the costs of lens production.

FormLabs Stereolithography 3D, in Figure 3.34, was used to print lenses directly. It uses a clear resin as material print. Several tests were done to find the best possible transparency, in particular changing the resolution of printing and the print angle on the build platform. The best solution was obtained with the resolution of 0.025mm on z-axis for the 3D printing, and printing the piece at $45°$ on the build platform, but none of these procedures worked, as the lenses were no opaque afterwards.

Figure 3.34: FormLabs Form 2 3D Printer

The only treatment that worked was polished lens and coating them with a transparency paint, in this way the lens's transparency improved dramatically. Figures belows illustrate the several improvements about the lens's transparency. In particular Figure 3.35 shows the original lens after the print, instead Figure 3.36 shows the same lens of Figure 3.35 but polish and finished with a transparent paint.

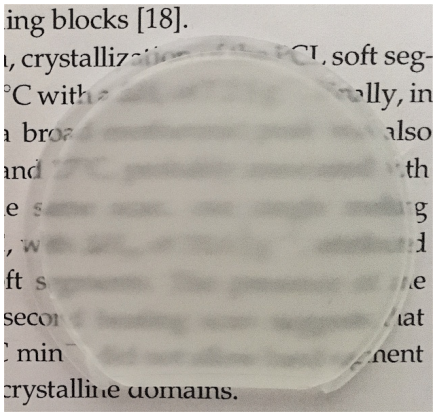

Figure 3.35: 3D-printed lens original

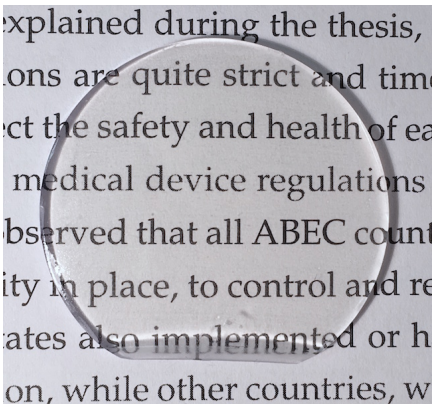

Figure 3.36: 3D-printed lens polishes

Numerous enhancements on transparency of lenses have been conducted though there is still space for further improvements because, as Figure 3.37 illustrates, the vision suffers the consequences of moving away.

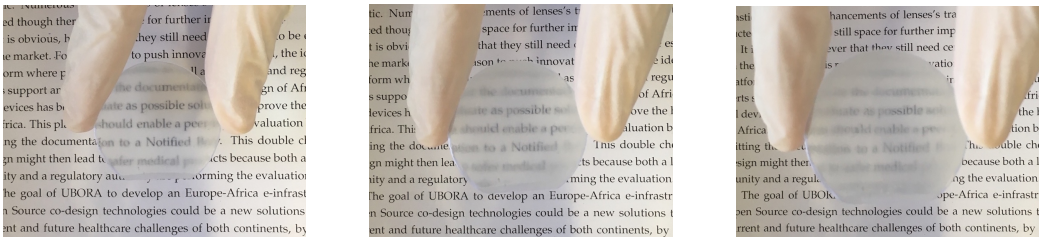

Figure 3.37: Vision with lens

3.6.9 Evaluation Parameters of the Spectacles

To analyze the spectacles, the Evaluation Table 3.9 [74] offers a quick sight of the main features of the device. I assigned a score considering my experience in prototype fabrication. The motivations of scores are explained in the list below.

Table 3.9: The evaluation parameters table applied to the spectacles

Faesability	**1**	**2**	**3**	**4**	**5**
Cheapness					x
Components and material availability					x
Construction time					x
Construction semplicity					x
Soundness					
Level of precision reachable				x	
Adaptability					x
Versatility					x
Usability	**1**	**2**	**3**	**4**	**5**
Level of components of users					x
Easiness of use					x
Possibility of reuse	x				
Management and safety	**1**	**2**	**3**	**4**	**5**
Level of competences of technicians					x
Number of maintenance interventions					x
Technical check					x

- The cost of the final product of these spectacles has been evaluate very low, comparing to the commercial glasses.
- Concerning the components and materials availability the scores are high because is only the material for the 3D printing is needed which you can buy directly from the websites of manufacturers of 3D printers.
- The "Construction time" and the "Construction simplicity" gained a score of 5 because the device is easy to be assembled, but it is important to notice that the use of the 3D printer obviously takes more time than a traditional industrial method of production. However, having small size objects, the estimated time is about two hours for the lenses and 3 hours for the frame.
- The soundness must be evaluate considering the actual limits about the transparency.

- The level of precision reachable gained a score of 4 because is necessary to consider the tolerance of the printers that is high but not to gain a score of 5.
- Adaptability gained a score of 5 because with the OpenSCAD software it is possible to fabricate a custom made spectacles.
- The two parameters relative to usability are all at high levels (score of 5) because the level of competences of users are very low, considering that only the input of few parameters is needed.
- Possibility in reuse is also low because the spectacles are patient specific.
- Finally, the maintenance and safety parameters gained high score, considering that the number of interventions are inexistent.

CHAPTER 4

Capacity building to improve the healthcare in Africa

The need for highly skilled personnel to address the ever increasing requirement in identifying, sourcing, installing, customizing, servicing and upgrading advanced medical devices and other technologies can not be overestimate. Currently, Africa depends not only on imports of medical devices but also of technical, scientific and professional services to keep this complex equipment in service. For these reasons improving BME capabilities has been taken into consideration as third approach to improve the healthcare in Africa. This chapter describes two direct experiences about BME capacity building in Africa.

1. Experience during the ABEC Innovators' Summer School in Ethiopia in January 2016.
2. Experience during the Amalthea Trust's training at Kyambogo University, Uganda, from April to May 2016,

Data described in this section were collected during these experiences or partially integrated with the past data collected by Amalthea Trust.

4.1 Building African biomedical engineering human capital

The main focus of this chapter is to highlight the importance of the training that countries with limited scientific, technological and industrial base can take to develop a robust medical devices industry. An innovative medical devices

industry is needed to provide key technical, business and professional services and value-added goods to the public and private health sectors.

Biomedical engineering in Africa has seen a very slow progress over the years. Many healthcare facilities lack an appropriately skilled technician to routinely maintain and repair medical equipment. This has in turn created a demand that some training institutes have responded to by providing biomedical engineering training at diploma and degree level. Previously, the demand for biomedical engineering services was partially satisfied by trained electricians and electrical engineers with very limited skills in medical devices management.

In Uganda for example, a number of private companies, both local and international, have tried to meet the demand through supplying equipment and holding service contracts with different health facilities. However, their high charges have led to many public healthcare facilities abandoning their services. The process is also very time consuming since the technicians are usually based in the capital city, and can take months before they get to health facilities in remote areas. It is also very common to have technicians flown in from countries such as Kenya, South Africa or even Europe to service or repair equipment. There are even cases of when equipment are returned to the suppliers in different countries to service, calibrate or repair.

The lack of skilled personnel often turns out not only as low quality health care services but also as waste of resources, in terms of time and money. For example the Nyanza General Hospital, in Kenya, imported a brachytherapy equipment for cancer treatments in 2002 but by the end of 2002, it was reported to have 'broken down'. The hospital managed to raise the 1 million Ksh ($16,400) pre-payment to have engineers sent in to inspect the equipment in 2006. The equipment was finally inspected in October 2008 and the engineers found nothing wrong with it but that it was not properly operated [91].

Both Kenya and Uganda have experienced similar delays in the repair of major cancer treatment facilities in the last few years. This type of incidents highlights the urgent need for skilled human resources to keep complex medical devices in operation and being used properly and safely.

The need for producing skilled biomedical engineers is commonly recognized but it differs depending on the interest of the involved institutions. For instance, most of the early efforts in Africa seem to have focussed on training of technicians that could maintain medical devices in good working conditions. These have ranged from short-courses offered to qualified electricians and medical technicians at hospitals and laboratories, ad-hoc training of biomedical diploma pro-

grammes (e.g. in Zambia and Uganda), and established biomedical diploma training programmes (e.g. in Kenya).

Technicians and technologists play a pivotal role in maintenance and safe use of medical devices [92]. Figure 4.1 shows a group of Kyambogo University students during a practical lesson held by Amalthea Trust foundation.

Figure 4.1: Students of Kyambogo University during Amalthea Trust training

Anyway focusing the attention on the maintenance and repair is not the only way to improve the healthcare because it is necessary also to instill in the student the desire of growth and innovation. Both manufacturing and service firms are both important to the development of a competitive and innovative medical devices industry.

As time goes by Africa's youthful population will find a career in biomedical engineering research, innovation and business development rewarding. Hence, demand for higher education will continue to rise as the nascent medical devices industry and rapid expansion in health facilities will offer graduates in biomedical engineering decent employment opportunities.

4.2 Experience during ABEC Innovators' Summer School

The Innovators' Summer School (ISS) is an initiative of UNECA and its goal is the economic development of Africa by stimulating biomedical innovation and improving higher education [93].

Figure 4.2 shows a group of students and lecturer during the Innovators' Summer School in Nairobi in 2014.

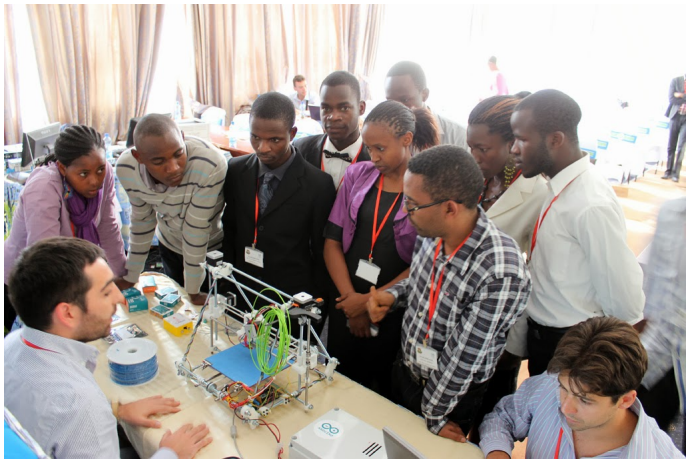

Figure 4.2: Innovators' Summer School in Nairobi 2014

The ISS is one week intensity activity that aims at nurturing the creativity and innovation in university students. The BME ISS is designed to:

- enhance the technical and engineering skills of students through exposure to new and emerging technologies and technology applications;
- build and stimulate the entrepreneurial competencies of students and researchers through training and hands-on lectures;
- encourage the emergence of multidisciplinary and multinational teams through strategic group building;
- instill the skills needed to promote and market innovative ideas and businesses.

Each student attending the Innovators Summer School (ISS) is selected on a competitive basis following a 6-9 months development phase that takes place at the participating universities. Each year, a theme is announced between January and April. Students hold brainstorming sessions and talks to identify health challenges, create a multidisciplinary team and design an engineering based solutions. The solution is first vetted at the university level and then submitted to an international panel composed of representatives of the participating universities, and industrial and technology development institutions in Africa and in Europe. The projects are reviewed and feedback is provided to respective student teams. The student teams get another opportunity to review and modify their project designs and concepts before making a final submission by September. A final assessment is made and up to 24 projects are then shortlisted. The teams whose

projects are selected can then choose one member to attend and represent the project at the ISS.

The ISS is specifically designed to help students learn how to create winning teams that meet the project requirement, being multidisciplinary and gender-diverse. It also encourages students to learn to mobilise and deploy different external sources of support (fellow students, researchers, hospitals and business leaders) to consult about their designs and to seek new knowledge and information.

Participating students in the one-week ISS are placed in groups of 3-4 and assigned 2 mentors from among the lecturers, researchers and industrial partners. These mentors will guide the students in the development of their design concepts. Students are required to attend all training sessions offered during the week and work on their projects at their own time.

4.2.1 History of Innovators' Summer School

The first exploratory summer school was held in Kampala (Kyambogo University) in 2012. During this event the participating universities formed the Africa Biomedical Engineering Consortium (ABEC) with the mission of bringing excellence to BME education in Africa. ABEC's logo, the result of a student design competition, is reported in Figure 4.3.

Figure 4.3: ABEC's logo

The second and third Innovators' Summer Schools were held in Nairobi at Kenyatta University in August 2013 and in Daresalaam in December 2014, respectively. The fourth Innovators' Summer School was held in Addis Ababa , Ethiopia, in January 11th-15th 2016. Here the focus was the application of mobile phones in healthcare product design and development [93].

In general, at least 400 students have participated in the design of innovative concepts and approximately 100 have attended ISS in the last 4 years. The ISS

awards served to focus the interest of students on their projects. In general, three awards are presented to honour:

- most Innovative Concept,
- concept with High Social Impact,
- concept with High Economic Impact.

2^{nd} Summer School: Introduction to Biomedical Device Regulations and Rapid Prototyping

Here the focus was on a series of intensive courses to demonstrate the potential of regulated open source design, prototyping and innovation to students, academics and regulators/decision makers. Over 35 students, technicians and lecturers per year from Kenyatta University (Kenya), University of Nairobi (Kenya), University of Eldoret (Kenya), Addis Ababa University (Ethiopia), Makerere University (Uganda), Kyambogo University (Uganda), Mbarara University (Uganda), University of Malawi (Malawi), Muhimbili University of Health an Allied Sciences (Tanzania), University of Zambia (Zambia) and University of Pisa (Italy) attended the courses.

After introductory lessons to explain the aim of the course, and some basics on rapid prototyping hardware, software, electronics, and safety regulations, hands-on sessions were provided, giving to the students the opportunity to learn by doing. During the course were underlined the importance of needs-based design and development, focusing on the respiratory problems of new born premature babies and the monitoring of breathing and body temperature. Here the goal was to design and build a low cost device, for monitoring respiratory movements and temperature, able to shake the cot to resuscitate the normal breathing of the baby when it stops, and equipped with a sound and light alarm to call a nurse to the cot. The implementation of these features was established together with students, after an intense brainstorming session. Importance was given to the functional aspects of the devices as well as their cost, feasibility safety and reliability. Students were divided into groups devoted to the study of: needs based design, safety and ISO compliance electronics, and prototyping.

At the end of the course an evaluation survey was conducted by the funders. The results indicated that only one participant had previously been exposed to open source technology. All participants expressed extreme satisfaction in the course, although more than half of them could have benefited from previous

knowledge on electronics, CAD and programming. There was also interest in the regulatory aspects and standards in medical devices. As the participants were from different backgrounds, many had very little idea what medical devices are and the critical importance of safety issues in such devices. The action thus served to bring home the importance of this aspect during the design of instruments for BME. To encourage safe design and innovation, the summer school ended with a student project competition organised by ABEC. With the help of lecturers and mentors, students were encouraged to spend the next year working on their own ideas for presentation at the following summer school [93].

3^{rd} Summer School: From Making to Marketing

The summer school in Daresalaam was hosted by the Muhimbili University of Health and Allied Sciences and was jointly run by the University of Pisa and SIDO (Tanzanian Small Industries Development Organization), who regularly hold courses on business development. The objective of the school was to design a simple device (a small ultraviolet sterilizer) and take it through the product development, business planning and marketing stages. The course began with a presentation and preliminary assessment of all student projects. Then the UV sterilizer was examined from a technical and design point of view, comparing its performance and safety with other sterilizer devices. Locally available materials and resources were selected for fabricating the device and students were allocated small components to design, prototype and assemble. In parallel experts on intellectual property protection, business planning, and marketing from SIDO showed the students how to take a product through all the phases of medical technology innovation and business development (identify, invent, and implement). With the concepts in place, students were given the opportunity to work in groups and present their business and marketing strategies for the product or products they had been working on for the competition. On the last day of the summer school the students re-presented their projects in a 10 minute pitch; the difference between the pitch and the first day's presentation was remarkable, and clearly demonstrated the impact of the 4 days of training and mentoring. Once again the response from students, professors and technicians involved in the school was enthusiastic [93].

4^{th} Summer School: Application of mobile phones in healthcare product design and development

The ISS 2016, Figure 4.4, programme focused on building the technical skills of students from 13 African universities on the application of mobile telephony in the design of medical devices. At the end of the programme, students and researchers would have been empowered with modern critical skills and techniques on how to enable smartphone to serve as a life-saving medical device.

Figure 4.4: 2016 ISS in Addis Ababa

In 2015, about 42 projects by 108 students with a focus on maternal health solutions and technologies to help prevent the spread of viral diseases (e.g. Cholera, Ebola, etc.) were received from 13 universities across Africa, and two projects from Europe. Of these, 24 were represented at the ISS 2016 in Addis Ababa, Ethiopia, by at least one student.

4.2.2 Surveys results collected during the ISS

To evaluate the impacts of the ISS on the African students it is necessary to understand what the students and lecturers think about it. Through a questionnaire shown in Appendix L, I collected the data during my experiences in Ethiopia. The most important results are listed below. Results consider 33 people interviewed.

Profession of people interviewed

Figure 4.5 shows the profession of people interviewed during the ISS in Addis Ababa.

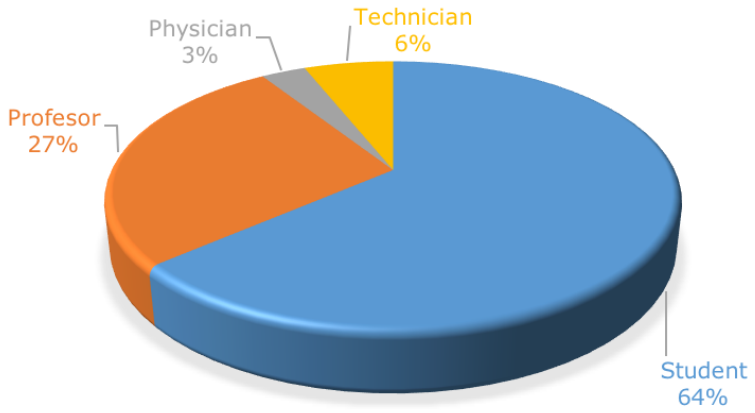

Figure 4.5: Background of interviewed

Opinion about the ISS

The interviewed reactions when asked about the opinion about the ISS are presented in Figure 4.6. They were asked to scale the impact on a scale of one (1) to five (5), 1 being not useful at all and 5 being very useful.

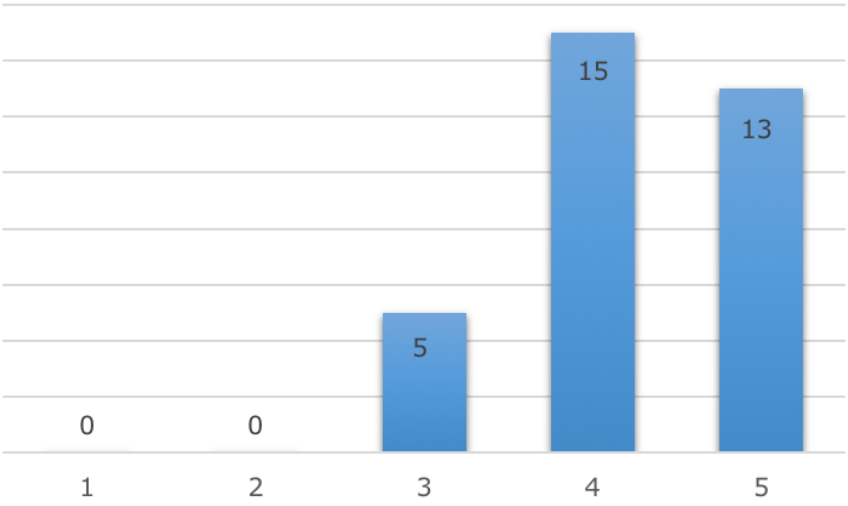

Figure 4.6: Opinion about the ISS of interviewed in Addis Ababa

Listed below there are the most frequent improvement proposals for the ISS.

- Invite researchers for the last day of summer school.
- Liaise with market designer to develop the final products of the student proposal.
- Improvement about the organization.

- Increased participation of the students.
- More lecturers to change the lesson's topics.

Personal interest about the repair of biomedical devices

The interviewed reactions when asked about the interest about the repair of biomedical device are presented in Figure 4.7. They were asked to scale their interest on a scale of one (1) to five (5), 1 being not interested at all and 5 being very interested.

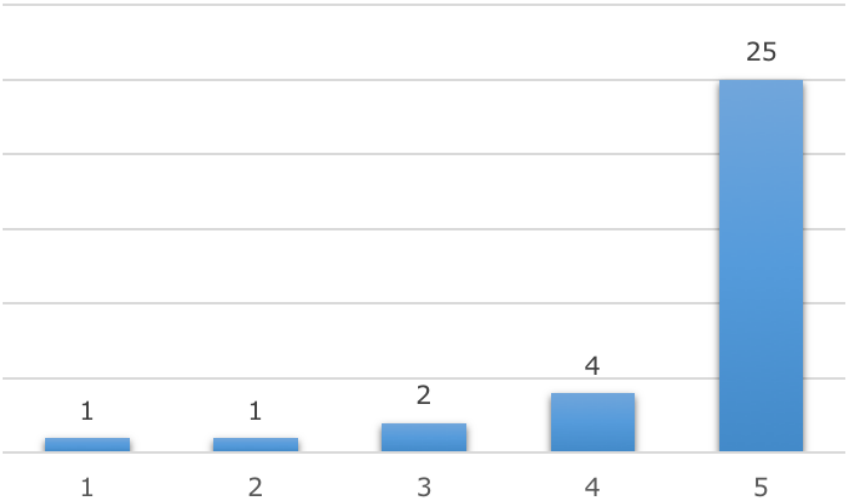

Figure 4.7: Opinion about the repair of biomedical devices of interviewed in Addis Ababa

Choice based on personal interest between design and repair of biomedical equipments

Figure 4.8 show the personal interest of people interviewed in Addis Ababa about the Design of medical devices or Repair Biomedical devices.

Opinion about biomedical technicians' skills in Africa

The reactions when asked about the opinion about the African technicians skills are presented in Figure 4.9. They were asked to scale the preparation on a scale of one (1) to five (5), 1 being not prepared at all and 5 being very prepared.

Proposals from people interviewed to improve the biomedical technicians's skills are listed below.

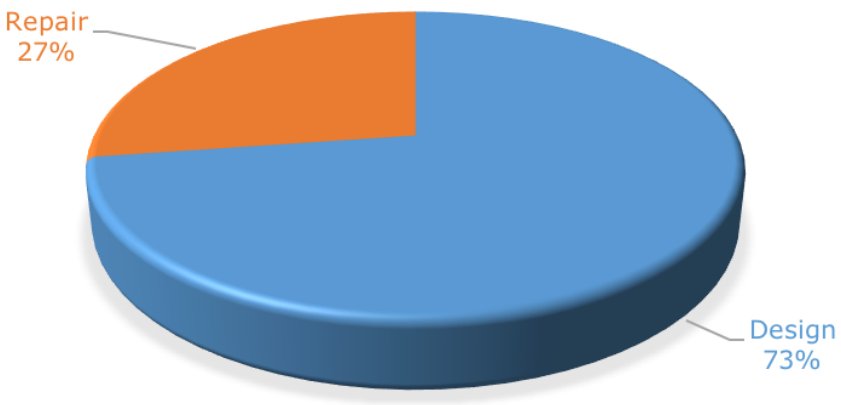

Figure 4.8: Choice between design and repair

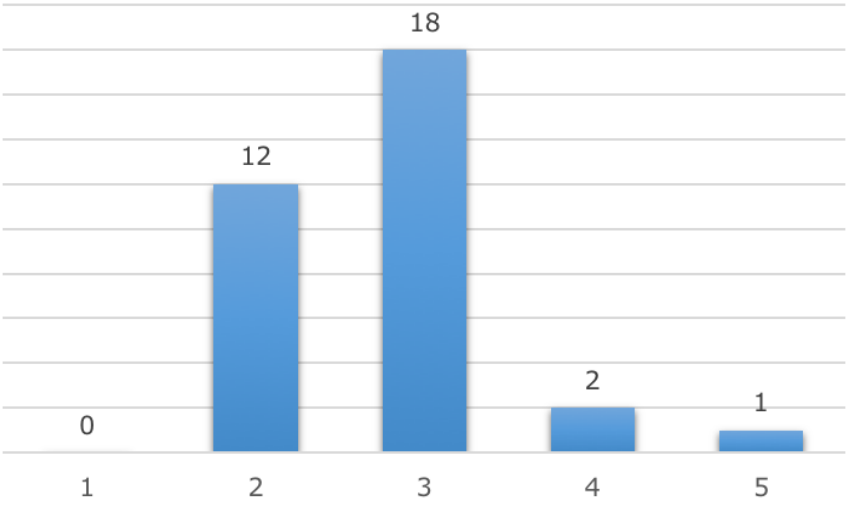

Figure 4.9: Opinion about the technicians' skills from Uganda interviewed

- Organizing of training workshop repairing particular equipment;
- provision of user manual for the new devices;
- African biomedical technician should be able to do preventive plan maintenance frequently;
- organizing competition in biomedical engineering field;
- technicians should be practical oriented;
- establish a platform to give full information about designing and partly with repairing.

Opinion about the importance of biomedical equipments donated in Africa

The students reactions when asked about the importance of biomedical equipments donated in Africa are in Figure 4.10. They were asked to scale the preparation on a scale of one (1) to five (5), 1 being not important at all and 5 being very important.

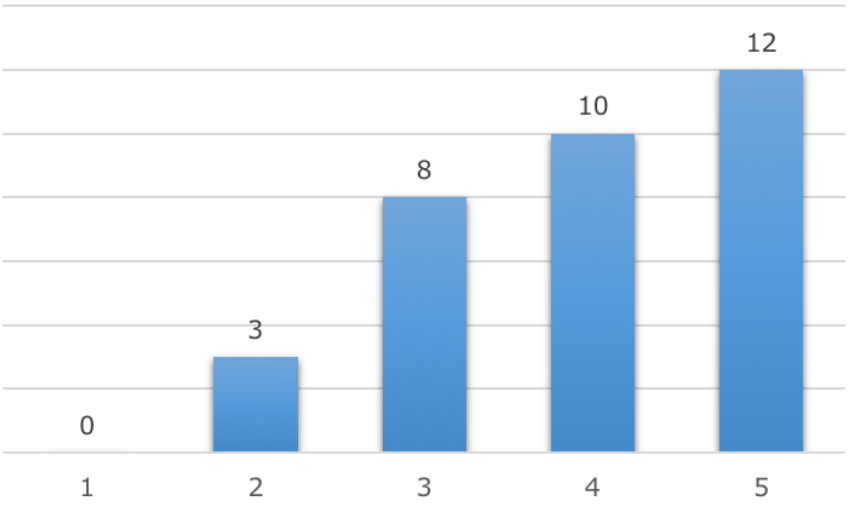

Figure 4.10: Opinion about donated equipment during ISS in Addis Ababa

4.2.3 Lessons learnt from Innovators' Summer School

Several key lessons, positive and negative, could be highlighted from the experiences of ISS. They are listed below.

- **ISS organization**
  The ISS experiences have shown a remarkable lack in organization. The ISS that was supposed to be held in December 2015 was postponed in January 2016 and the same situation occurred this year for the ISS in Egypt. Changing the programs at the last minute denote lack of interest from the organizing partner. It is important that the deadlines are met also for reasons of credibility against other partners.

- **Teaching material**
  Every year it is required to participants to install some programs on their computer to support the training before to attending the ISS. Installation files and relative instructions are uploaded, a lot of time before the ISS, in shared folders with all participants but a lot of students don't do their work.

During the 2016 ISS in Addis Ababa we spent the first whole day to install programs that the students should have had already on their computers.

- **Universities limits**
  While the ISS has become popular and the projects submitted annually have increasingly scientifically and technically sound, the limited availability of research and fabrication facilities at universities hindered students from developing prototypes.

- **Lack of communication**
  Kyambogo University is one of ABEC founder, but, during my experience in Uganda, when I asked to the students why none of them participated to the last ISS in Ethiopia they replied that none of them knew what it was. This is a clear symptom of lack of communication between ABEC referent and students. In this way students lose big chances and with them also the belonging University. Informing students is an obligation of ABEC members.

- **Female component growth**
  The international nature of the ISS encourages teams to engage beyond their institutions and countries. This is built in the requirement of team formation, which requires teams to be multidisciplinary, multinational and gender-diverse. For instance, some the innovation awards were won by female-proposed concepts and major changes in project designs over a week often happened in teams with members from different backgrounds.

- **Involvement of industry**
  The involvement of industry and industrial research institutions has played a positive role, especially in demonstrating entrepreneurial and employment opportunities. In addition of providing practical skills, they show how small but critical improvements to existing systems, gaps in current designs and new applications can spur new businesses and major improvements in health service delivery.

4.3 Amalthea Trust Foundation

Amalthea Trust is a charity and it is particularly concerned with the lack of trained technicians and engineers in many developing countries, it's goal is to help provide for the sustainable maintenance of medical equipment through the

provision of training programmes for the recipients, including test equipment and workshop facilities.

With most initiatives focusing on donation of equipment, flying out local technicians to teach about one or two devices, Amalthea Trust decided to take a different approach, it decided to carry out a comprehensive needs assessment to establish the cause of problems with medical equipment in Uganda and similar countries. They realized that skills and knowledge were missing to enable appropriate service and repair of these equipments. This UK registered charity noticed that the lack of trained technicians and engineers in low resource countries meant that the majority of the equipment were rendered unusable due to simple faults, such as a blown fuse. They identified that in order to reverse the general trend of equipment breaking down shortly after they were bought, there was a need to locally equip people with the right skills. They realized that among other reasons, lack of appropriately trained technicians was the major cause of poor equipment conditions.

After evaluating different challenges attached to medical equipment management in Uganda, Amalthea Trust decided to support a diploma training technicians at Kyambogo University. They developed a memorandum of understanding with the Ministry of Health to recruit some of the technicians after they finished their two year diploma. They helped to equip the workshops as well as bringing engineers with a wealth of experience to train the local students. The diploma has since yielded about 40 graduates all working in different places, mainly in healthcare, around Uganda. Some of these graduating are shown in Figure 4.11

Figure 4.11: Graduating student at Kyambogo University

4.3.1 The Kyambogo Diploma

Before the diploma was set up at Kyambogo, there was a BMET diploma offered at Ernest Cook Ultrasound Research and Education Institute (ECRUEI); however, this was not accredited by the Ministry of Health and was too expensive for many local students. At around the same time as the Kyambogo diploma was set up, Makerere University also started a degree programme. Both the diploma and degree faced similar challenges such as lack of lecturers, tutors and technicians, they also lacked dedicated laboratories for use in training biomedical technicians. Through the support of the Amalthea Trust, the diploma training was helped with training the local trainers, developing course materials as well advising about the structure of the training.

This limitation has resulted to very low yields of skilled biomedical technicians. After seeing a gap in the field, the Ministry of Health agreed with Kyambogo University to start a two-year diploma in biomedical engineering. This was started in 2010 and it has since produced more than 40 technicians working in different hospitals and companies around the country. In search for innovators in the field of Biomedical Engineering, the then Dean of the School of Biomedical Sciences, Makerere University, Professor Charles Ibingira initiated the idea of training Biomedical Engineers at degree level. The Bachelor of Science in biomedical engineering was introduced at the Makerere University, College of health sciences in 2011 with twenty students. Similar to the programme at Kyambogo, Makerere University has collaborations with other institutions around the world to support the 4 years program.

The Diploma attracts students from different backgrounds as Figure 4.12 shows.

The majority of students (50%) enrolled directly after finishing their A levels. The other students took the diploma after they had been working for some time. Some of these were working in the biomedical engineering related fields while others were in different fields and wanted a change of career. A few of the rest had diplomas (18%) and certificates (19%) in courses like clinical medicine, radio and TV repair and maintenance and electrical engineering while the rest had more advanced education. It was noted that several of the students had prior biomedical engineering or clinical medicine exposure, which enabled them undertake the training better, having the ability to relate to situations in clinical settings.

The Diploma in Biomedical Engineering offered at Kyambogo University lasts two years. It has many modules as Table 4.1 illustrates.

The training combines principles of Engineering and Medicine to prepare stu-

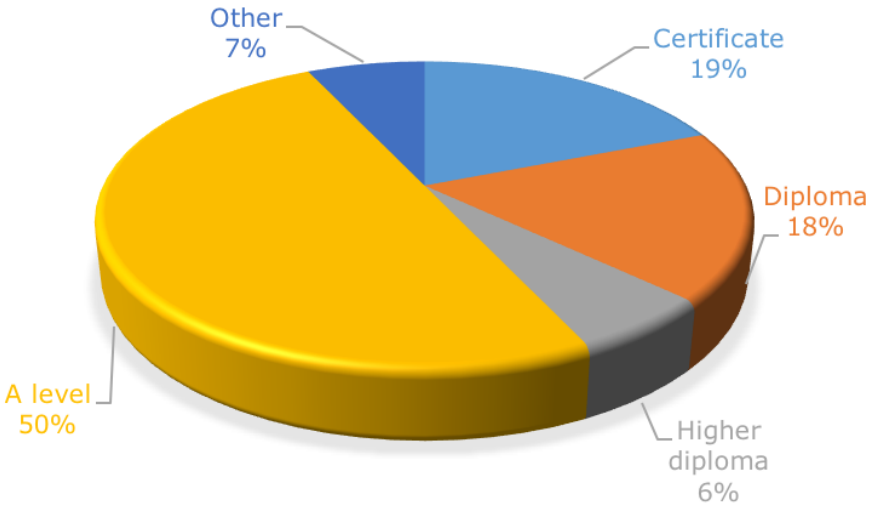

Figure 4.12: Trainees' education prior to attending the Amalthea Trust training

dents for working with equipment in a hospital environment. There are practical activities mainly supported by UK Engineers volunteering through the Amalthea Trust, see Figure 4.13. The students also have elements of internship/ hospital training at the end of the first academic year so that they become familiar with the environment where they will be working.

Figure 4.13: Biomedical Engineering students

The number of graduates has reduced since the program was started as illustrated in Figure 4.14. There were 17 graduates in 2012 who reduced to 9 in 2013 and to 8 in 2014. The reasons to this decrease have been highlighted throughout this study. The graduates believe that factors such as high tuition fees and the absence of an evening part-time program means that a number of students

Table 4.1: Diploma course at Kyambogo University

	Course
Year one: Semester one	Communication skills and humanities for biomedical engineers
	Essential mathematics I
	Introduction to biochemistry and medical physics
	Functional anatomy and physiology
	Introduction to electrical engineering science
	Mechanical drawing
Year one: Semester two	Essential mathematics II
	Bio fluid mechanics
	Principles of biomedical measurement and instrumentation
	Electrical engineering drawing
	Computer technology and ICT
	Workshop practice
	Electronics
	Hospital enviroment
	Hospital training
Year two: Semester one	Biomedical equipment I
	Applied biomedical measurement
	Fundamental electrical technology
	Fundamental mechanical technology
	Digital and microprocessor technology
Year two: Semester two	Biomedical equipment II
	Assistive technology
	Entrepreneurship and management skills
	Group project

cannot undertake the program. There are some technicians who have jobs and would like to improve their knowledge, skills and qualifications but the program hours coincide with their working schedule and cannot afford to take two years off from their work to take the diploma.

4.3.2 My experience with Amalthea Trust

It was very important to understand the importance of the technicians's capacity building to improve the healthcare in Africa. For this reason through Erasmus+ Traineeships program, which supported my period abroad, I spent three months in England working in partnership with Amalthea Trust. Experience in Amalthea Trust started in February with a period of training at Hilditch Group

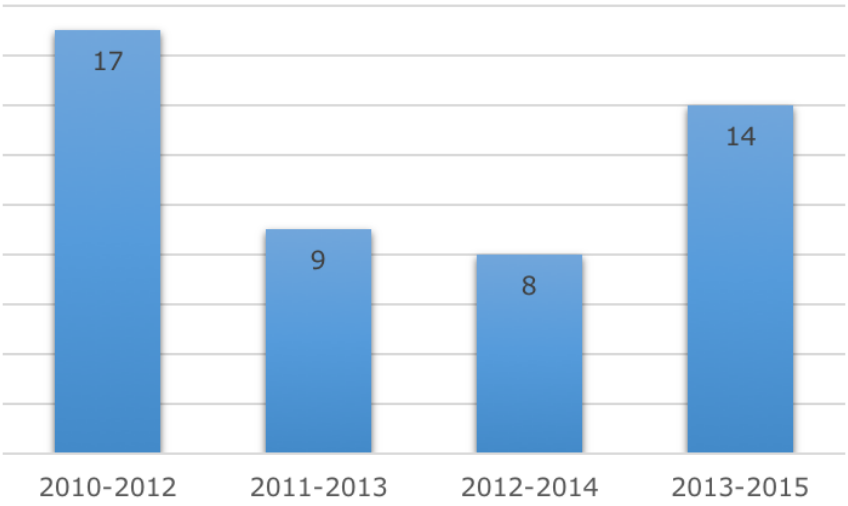

Figure 4.14: Graduated students since the beginning

Ltd in Malmesbury, England, where I learned the basics to repair biomedical devices as shown in Figure 4.15.

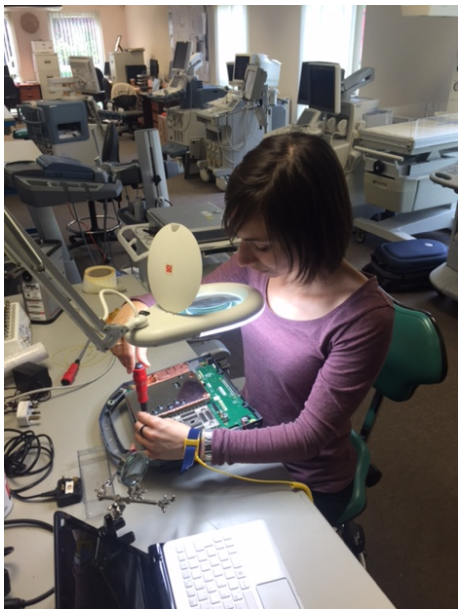

Figure 4.15: Hilditch Group Ltd Medical Engineering Office

During this period I worked side by biomedical engineers experienced in the repair, maintenance and certification of medical devices. The most commonly considered devices were ultrasound equipment, equipment for colonoscopy, patient monitors, incubators and C-arms. During the period of training at Hilditch Group, I also prepared the lessons regarding ultrasound machine and X-ray machine that I used as teaching material during the lessons that I conducted for the

Biomedical Engineering Course at Kyambogo University in Uganda. After my training in England I went in Uganda, as a volunteer, for 4 weeks, with other two volunteers: Jaswant Bhilku and Satish Taker. In this period we trained students about the ultrasound machine and X-ray machine.

Period of lessons started on 11th of April until 6th of May, firsts two weeks to explain the Ultrasound machine and the seconds two weeks to explain the X-ray machine. Lessons stared at 9:00 am and finished at 5:00 pm, every day from Monday to Friday, with 1 hour from 13:00 to 14:00 for the lunch break. The number of students changed every day. They usually were 10 in the class, 6 boys ans 4 girls, but the class was composed of 23 students.

We started with the Ultrasound module, and volunteers for this part of the course were Jaswant Bilkhu and me. I did the theorical part during the morning, while Jaswant aided where necessary and lead the practical aspect of the module in the afternoon. At the end of the Ultrasound module I realized an evaluation test for students attached in Appendix J.

Satish Thaker, arrived two weeks later to offer his expertise in the X-ray module. As before I explained the theorical part of the X-ray during the morning and Satish the practical part in the afternoon, and also for the X-ray module I realized the evaluation test for the students, attached in Appendix K.

During our training the students took on a trip to Mengo Hospital on Wednesday 27th April, where they saw two of the X-ray machine types that they learned about earlier in the week. During the visit at Mengo Hospital the students were 15. Satish was also able to point out a lot of the device components and explain them in a little more detail.

We also arranged for them a visit to Mbale Hospital a week later. The students during the visit to Mbale were 16. They saw the orthopedic outpatients department, artificial limb construction (as shown in Figure 4.16), physiotherapy, dental, and pathology departments.

They managed some repairs on the broken equipment in the dental department, they made a lot of progress on these, unfortunately there was not enough time to complete all repairs. It was also good to see two ex-student that now work at Mbale Hospital in Kampala. Amalthea Trust is glad they have found employment in one of their national hospital, working hard to ensure equipment is functioning correctly and safe to use. This is exactly what we are working towards.

Publicity is important if you want to make the world a better place, so Amalthea Trust was happy to have Callum Barre, journalist freelance, join us in Uganda, as

Figure 4.16: Artificial limb construction at Mbale Hospital

he made a short promotional film about the work Amalthea Trust are doing, as shown in Figure 4.17 [94]. The promotional film is now available on Youtube at https://www.youtube.com/watch?v=X2z9Vjn_PE4.

Figure 4.17: Working progress for Amalthea Trust's promotional documentary

4.3.3 Surveys results collected during the training in Uganda

During my experience in Uganda I asked to the student the reasons for choosing to study the diploma. A total of 27 students were interviewed using the survey in Appendix L but furthermore I collected personal annotations. The major-

ity stated their desire to work in a health facility and they saw the diploma as a wonderful conduit to meet their goals. They also pointed to the fact that there is general lack of qualified biomedical engineers and technicians in Uganda, leading to poor healthcare provision due to the high numbers of broken equipment. They saw the diploma as a route of providing them with skills that were highly in demand and therefore they would easily find jobs. For some, the diploma also presented an opportunity to expand their experience and skills in medical device management. A small percentage of students stated that their love in combining engineering and medicine for choosing the program. Some sought advice from friends and relatives who told them that it was a good course and considering that it was new, the job prospects would be high. Others, especially those who already had jobs were attracted due to the short duration for the course. Being Biomedical engineering in Uganda presented them a good opportunity to create international relationships with other biomedical engineers around the world through their support and increase their chances of working abroad.

The technicians generally felt that they needed to enhance their opportunities in the Biomedical Engineering. A high number were planning to undertake a degree in the next five years so that they can get positions that would enable them to influence and bring about change in this new field. There was a suggestion that Kyambogo University starts a Degree program in Biomedical Engineering because it is has access to equipment and the support from Amalthea Trust. Some of the more ambitious graduates want to start companies addressing the unmet needs in medical devices management looking to go into consultation, sales and servicing of equipment. There was a small section of graduates who are considering constructing healthcare facilities with well managed medical equipment to demonstrate the importance of biomedical technicians in the country.

Employment after studying

The technicians who had so far graduated from the diploma training have all ended up employed. The figure 4.18 below shows the number of graduates and where they are currently employed. The data were collected from Amalthea Trust and integrated with mine. The places of employment have been divided into Private Medical Facilities, Government Medical Facilities, Non-Medical Facilities and others. Non-medical facilities include telecommunication companies and banks. The others entry contains technicians who cannot be traced. The majority of the graduates got jobs as technicians in either healthcare facilities or private companies in the field.

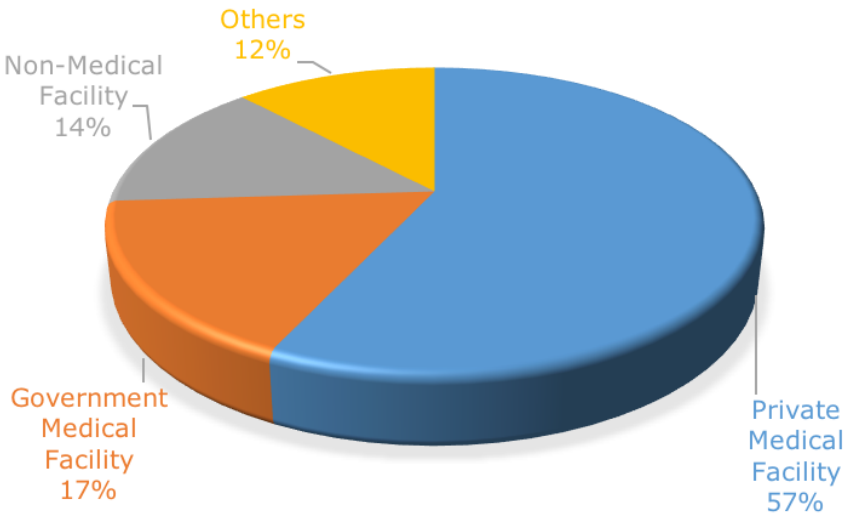

Figure 4.18: Currently employment of technicians

From Figure 4.18, it is evident that the number of technicians working for the private sector is higher compared to that working for the government sector. There are recognized benefits of Amalthea Trust's involvement with training of technicians at Kyambogo University. The interviews show that the technicians greatly value the confidence they gain as a direct result of interacting with the Amalthea Trust volunteers given their vast experiences. The graduate students feel that they needed better support to fit in the system, which at this time needs building as well. The lack of structures means that the graduates might get lost in the big system especially when they find a 'broken one'. It is very challenging to be the only person against everyone else in an organization. Areas such as training for management, continuous profession development, sharing experiences where identified among others as those needing attention to improve the practice of biomedical engineering in Uganda.

Availability of resources

When asked about the resources they needed to effectively carry out their work, the technicians' responses were varied and included:

- Access to complete tool boxes and reliable spare parts. They reported that most of the time the tools and spare parts available on the Ugandan market are either substandard or at hiked prices. This in effect hinders work since one has to wait till the spare was available or till the required tool was found. Sometimes the medical equipment has to be replaced totally, which was unfavourable considering the low budget allocated to the health sector.

- Access to information on specialised medical equipment especially imaging equipment such as X-ray machines. According to the technicians, the service manuals of some equipment came in other languages or did not contain detailed information on the subject. Most times only the user manual is available, with scanty troubleshooting information. This hindered the work of the technicians who resorted to lengthy trial and error methods which many times, actually ended up ruining the machine. They reported that they needed the information in form of research books, video tutorials about various machine models for operation and troubleshooting.

- They also pointed to the lack of a platform to source knowledge and information. They said that a website could act as this platform for encouraging mentorship and consultation of various biomedical engineers and technicians in case one encountered a problem.

- The internet and fast computers are the other resources required by the technicians in their work mainly for research, database management. They felt that they needed to be connected to the world in order to access information that will help them improve at their work places.

- Creation or purchasing of an equipment software database management system for purposes of creating inventory and accurate reports for their work places would go a long way in organising their work.

- Follow up support training on subjects such as the latest technology medical equipment and regarding some laboratory equipment as well as areas where the technicians felt they need more support would be a very useful resource. Also, training in areas of hospital management skills like project planning and management was identified as important. There was a request to introduce a biomedical engineering bachelor's degree programme in Kyambogo University.

- In regard to supporting their careers, the technicians requested that the Amalthea trust recommend them to bigger professional organisations in order to build their experience.

Influence of the Amalthea Trust involvement

Through data collected from Amalthea it was possible evaluate the diploma impact in terms of the following parameters:

- its usefulness in the trainees' daily work,
- its effect on increasing the trainees' willingness to train and mentor others,
- its effect on increasing the trainees' ability to train and mentor others.

The technicians' reactions are presented in Figure 4.19. They were asked to scale the impact on a scale of one (1) to five (5), 1 being not useful at all and 5 being very useful.

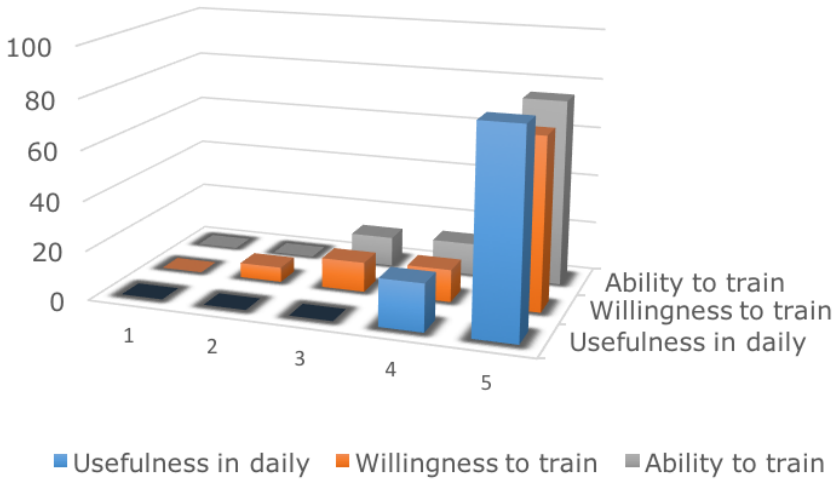

Figure 4.19: Impacts of Amalthea Trust on the technicians

From the results in Figure 4.19, 81.25% of the respondents said that the training was very useful in their daily work while the remaining 18.75% returned a scale of 4 regarding the usefulness in daily work. 68.75% of the respondents rated the training very useful in terms of increasing their willingness to train others while 12.5% gave a rating of 4 and only 6.25% deemed it fairly useful with a scale of 2 and the rest rated it at 3. Concerning increasing the trainees' ability to train and mentor others, 75.0% of the participants agreed that the training increased their ability to train and mentor their fellow students with a top rating of 5 and others while the ratings of 4 and 2 both got a 12.5% respondent selection.

The technicians felt that it was easy promoting their Diploma to prospective employers since it had the element of support from experienced engineers. On the other hand, the technicians thought that the training could be improved. They pointed to the lack of local trainers and tutors in the specialised biomedical engineering units which meant that they did not get full year support in the areas. They however pointed out that when the UK engineers were around, they received all the necessary support.

During this period I submitted to students the same survey used during the ISS attached in Appendix L, the most important results are listed below.

Opinion about the ISS

The students' reactions when asked about the opinion about the ISS are presented in Figure 4.20. They were asked to scale the impact on a scale of one (1) to five (5), 1 being not useful at all and 5 being very useful.

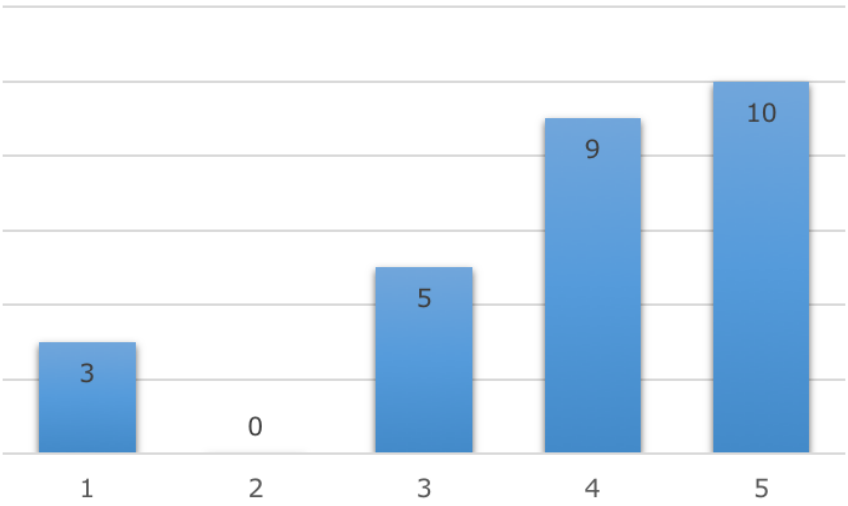

Figure 4.20: Opinion about the ISS of Kyambogo students

Opinion about technicians' skills in Africa

The students' reactions when asked about the opinion about the African technicians' skills are presented in Figure 4.21. They were asked to scale the preparation on a scale of one (1) to five (5), 1 being not prepared at all and 5 being very prepared.

Opinion about donated equipments

The students' reactions when asked about the importance of biomedical equipments donated in Africa are in Figure 4.22. They were asked to scale the preparation on a scale of one (1) to five (5), 1 being not important at all and 5 being very important.

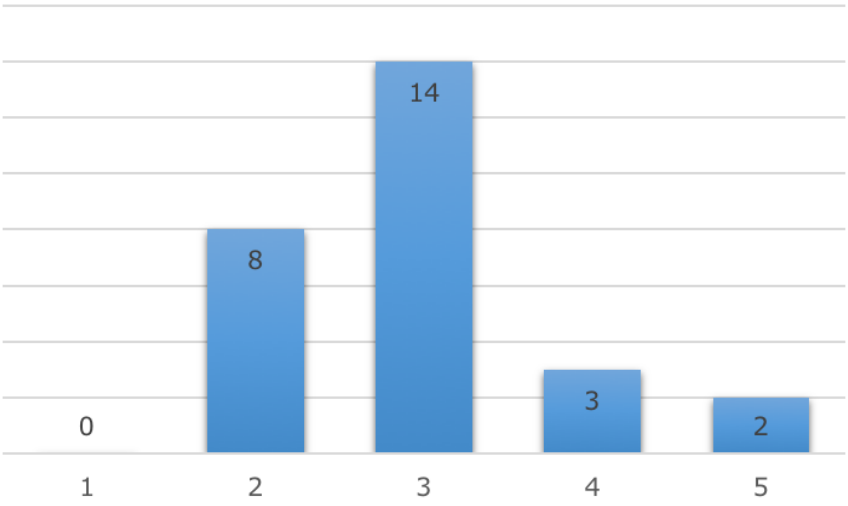

Figure 4.21: Opinion about the technicians' skills from Uganda interviewed

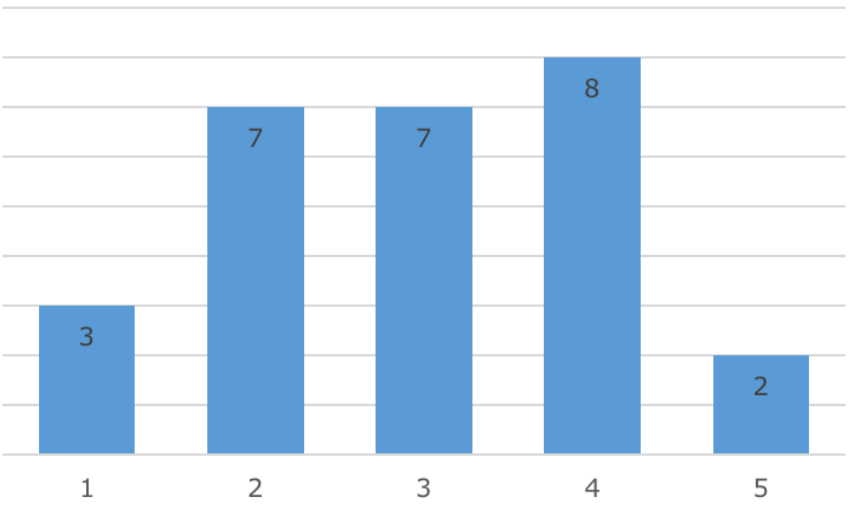

Figure 4.22: Opinion about donated equipment in Uganda

4.4 Comparison of results

During this section will be compared the survey's results collected in the two experiences in Africa. From the graph shows in Figure 4.6 is evident that the overall opinion abut the ISS is positive despite the negative aspects highlighted before. This is probably due a momentary enthusiasm because the interviewed were attended the ISS. The results collected in the graph of Figure **??**, show the same question submitted three months later my experience in Ethiopia to students that have never attended the ISS, suggesting that also this interviewer consider the ISS a great opportunity to improve their knowledges, capabilities and to debate

interesting topics. If the results shown in the in Figure 4.6 cab be influenced by a momentary enthusiasm the results in the graph in Figure **??** cannot.

About the comparison between the results shown in Figure 4.9 and in Figure 4.21, they confirm that the opinion about technicians's skill are not good. It is important highlight that the results don't concern only the situation in two countries, Ethiopia and Uganda, but they describe the opinion of technicians's skill in 7 different countries in Africa because it is important consider that the people interviewed during the ISS are from Malawi, Uganda, Ethiopia, Egypt, Tanzania, Kenya and Nigeria.

Comparing the results about the opinion of donated equipment, graphs in Figure 4.10 and 4.22, those collected during the ISS are better that those collected in Uganda. My opinion about this is that if the interviewed in Ethiopia principally were biomedical engineering students, the interviewer in Uganda were principally technicians and so more informed about the conditions and issues of donated equipment.

CHAPTER 5

Donation of medical devices to improve the healthcare in Africa

Medical equipment has become a fundamental part of modern healthcare delivery, enabling screening, prevention, diagnostics, treatment and palliative care. Still a huge mismatch exists between the number of technologies produced by the global healthcare innovation community and the user in low-resource settings. Donations of medical equipment could bridge some of these gaps, allowing for some of the surplus from high resource settings to be passed to low resource settings. However, if poorly executed, donations could turn into a burden for the recipient, wasting an enormous amount of money, human resources and time, with long term implications of crippled healthcare systems.

Chapter 5 describes the donation of medical devices as fourth approach to improve the healthcare in Africa. During my experience in Uganda I had the possibility to visit three different hospitals and see the conditions of donated equipments. After my way back in England I described in report for Amalthea Trust this finding.

5.1 Medical devices donations

The provision of modern healthcare is heavily dependent on technology, which includes healthcare equipment. Because of economic constraints, the health sectors of many developing countries have to rely considerably on donations of equipment. In some countries, nearly 80% of healthcare equipment is donated or funded by international donors or foreign governments. Although most donations are made with good intentions, the outcomes are not always positive if the donations are not properly planned and coordinated. The World Health Or-

ganization (WHO) estimates that as much as 80% of medical equipment in some countries is donated or funded through foreign sources, but only 60% of the donations are put into operation [95]. Reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training and lack of effective technical support. In many cases, donations circumvent the selection and procurement systems of the recipient country and institution, where such systems exist. Consequently, little consideration is taken of actual local requirements, the burden of disease and level of care, the number of user-staff and their capability, and the available level of technical expertise to provide maintenance. Even local manufacturer representatives and equipment distributors, who may be expected to provide after-sales support, are bypassed. Further difficulties related to the purchase of consumables and availability of spare parts, among many others, could transform the donated equipment into a liability, rather than an asset, to the recipient. Inadequate medical equipment donations are often due to a combination of the donor's lack of awareness of the particular challenges and needs of the end-users, and poor communication between donors and recipients about these challenges and needs.

Currently, WHO spells out the four principles of a good medical equipment donation to the mutual benefit of both donors and recipients [96].

1. Health care equipment donations should benefit the recipient to the maximum extent possible.

2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.

3. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

4. There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties.

"There is no question that you can donate effectively" says Robert Malkin, a professor of the practice of biomedical engineering at Duke University, adding the caveat that it takes a lot of effort to make sure everything is done right. For example, Malkin says organizations need to know what recipient hospitals or countries need. They also need to ensure the recipients have access to the right accessories and supplies to make the devices work properly. People need to be

trained to use the equipment and, of course, it also has to be shipped, delivered and installed. "That's a lot of things to get right, and you need to do that with every piece of equipment," he says [97].

5.2 Trip in Uganda

When we arrived in Uganda Jaswant Bilkhu and I stayed for two days in CoRSU Hospital in Entebbe Road. This is a charity hospital which treats some of the most challenging injuries from terrible burns to cleft palate surgery. During our training at Kyambogo University with the students we taken on a trip to Mengo Hospital thanks to a graduated students from University of Kyambogo and now employed to Mengo Hospital. To see the realty also in rural landscape we also arranged a visit to Mbale Hospital a week later.

The biggest problem highlighted during our visit was that most of the equipment is donated from all over the world include America, Australia, Japan and UK and as a consequence there are hundreds of different types of machine; all operate differently and require different spares. In the following subsection our visit to hospitals are briefly described.

5.2.1 CoRSU Rehabilitation Hospital

After our arrival in Entebbe, Jaswant Bilkhu and I spent two day at CoRSU Hospital which is a private non profit, non government organization in Uganda. We visited CoRSU (Comprehensive Rehabilitation Services for Uganda), see Figure 5.1, thanks Dr. Sarah Hodges & Dr. Andrew Hodges.

Andrew is currently practicing wide range of Plastic Surgery with particular interest in reconstruction including microsurgery, hand surgery and cleft surgery and Sarah is the Head of Anaesthetic department at CoRSU hospital. The CoRSU was quite impressive and no doubt well run and well equipped. Much of the medical equipment has been donated, some from National Health Service (NHS) hospitals but new sterilisers have been provided out of charity funds. Even though the hospital is well equipped they still do not have any facilities for repairing equipment and seem to be relying on visiting engineers to provide these skills.

We had a thorough tour of the hospital, starting in the Engineering Dept which shows the very basic facilities in their workshop. The problem seems to be that they have very ancient equipment and cannot get hold of spares, due to the age of the equipment and the cumbersome procurement process which has to

Figure 5.1: CoRSu Rehabilitation Hospital

be routed via the Ministry of Health in Uganda. They only have one member of staff who knows electronics.

5.2.2 Mengo Hospital

Mengo Hospital is the oldest Hospital in the country; today, the Hospital, in Figure 5.2, is an urban community Hospital with all the amenities of a modern hospital in sub-Saharan Africa. For instance it has a Dental Clinic which is ranked among, if not the best in the country. Similarly the Eye Clinic is well equipped and boasts of offering quality care services that are second to none in the country. The Hospital houses the Ernest Cook Radiology Department, named after Ernest Cook, the nephew of Albert Cook, who brought the first X-Ray machine to East Africa in 1907, and installed it at Mengo Hospital. The X-Ray department is located within the Sr. Albert Cook Building. ECUREI offers Ordinary and Advanced Diploma Courses in Ultrasonography.

5.2.3 Mbale Hospital

During the last week we went to Mabale Hospital, see Figure 5.3. It is a Government Regional Referral Hospital, situated about 250 km northeast of Kampala, Uganda's capital. It is a public hospital, funded by the Uganda Ministry of Health.

We had thorough tour of the hospital, starting to the rehabilitation center. It is a well stocked hospital able to hold up the health care needs of a city like Mbale, unlike the Mengo hospital and Mulago hospital against a big city like Kampala.

Figure 5.2: Mengo Hospital in Kampala

Figure 5.3: Mbale Referral Hospital

The new endoscopy service makes a big difference to the health prospects of a great many people. The problem was that 3 months before our visit all of endoscopy device were broken and nobody was able to repair them. They were a donation from some place in Europe that after the donation is not ensuring the maintenance of the device.

CHAPTER 6

Discussions

As a conclusion of my thesis this chapter concerns the deduced conclusions of four strategies described in previous chapters to improve the healthcare in Africa.

- Improving the regulatory environment of medical devices.
- Advantages Open Source technologies.
- Building the human capital base:
  - Training for Biomedical Engineering Students,
  - Training for Biomedical Engineering Technicians.
- Regulation on donated medical devices.

Through apposite tables the impacts related to the four approach s will be evaluate.

6.1 Improving the regulatory environment

Regulatory infrastructures and ethics committees are required to provide independent oversight and to ensure the enforcement of human rights treaties. Countries should ensure biomedical research ethics and safety committees are adequately funded both at national and institutional levels. Regulatory bodies stimulate research and innovation by providing advice on emerging safety concerns, alternative methods, cost-effective approaches and overall scientific guidance. If properly managed, regulatory agencies could help in driving innovation and ensure concerns are addressed in advance. Similarly, national and institutional intellectual property and technology transfer offices could help protect and commercialize research outputs.

European Directives for medical device regulations are quite strict and time-consuming but also essential in order to protect the safety and health of each individual. The research during my thesis work shows that African medical device regulations have an affinity to these European directives. It was observed that all ABEC countries already have a National Regulatory Authority in place to control and regulate medical devices. The majority of those states did also implement or harmonize directives to medical device regulation, while those countries who do not have a significant number of regulations have a huge interest to establish them in their legislation to provide access to safe, effective and quality medical products. However, due to limited human capacities in Biomedical Engineering most of the African countries cannot regulate medical devices properly.

To simplify regulatory processes and even save costs at the same safety level of medical devices, the question of Open Source Medical Devices as an alternative to the current processes was evaluated. During the study through two cases of study has been demonstrated that the Open Source Medical Devices might be an option, but they still need certification to be established on the market; on the other side, the idea of Standards Harmonization is evaluate in Figure 6.1.

As Figure 6.1 shows, regulatory authorities will benefit in terms of improved expertise, collaboration with other regulatory authorities and operational efficiency through sharing of information and recognition of established regulatory authority decisions. Healthcare professionals will benefit through the availability of more treatment options in order to optimise patient management. Biomedical industry will benefit through the establishment of new markets and the improved ability to comply with regulatory requirements related to devices registration. Patients will benefit through improved supply of devices, access to high quality devices that comply with stringent requirements of safety, quality and efficacy and reduced risk of use of broken devices.

6.2 Building innovative infrastructure for Open Source technologies

To encourage innovation, engineering students and innovators need tools with which to experiment. 'Fab labs' or 'design kitchens' are names given to laboratory/workshops that are well equipped and stocked with the basic materials and tools to design and make prototype devices. Students can work in groups to invent, design and test their own ideas. Students from engineering, health and other disciplines can join the groups and contribute to the ideas. Universities in

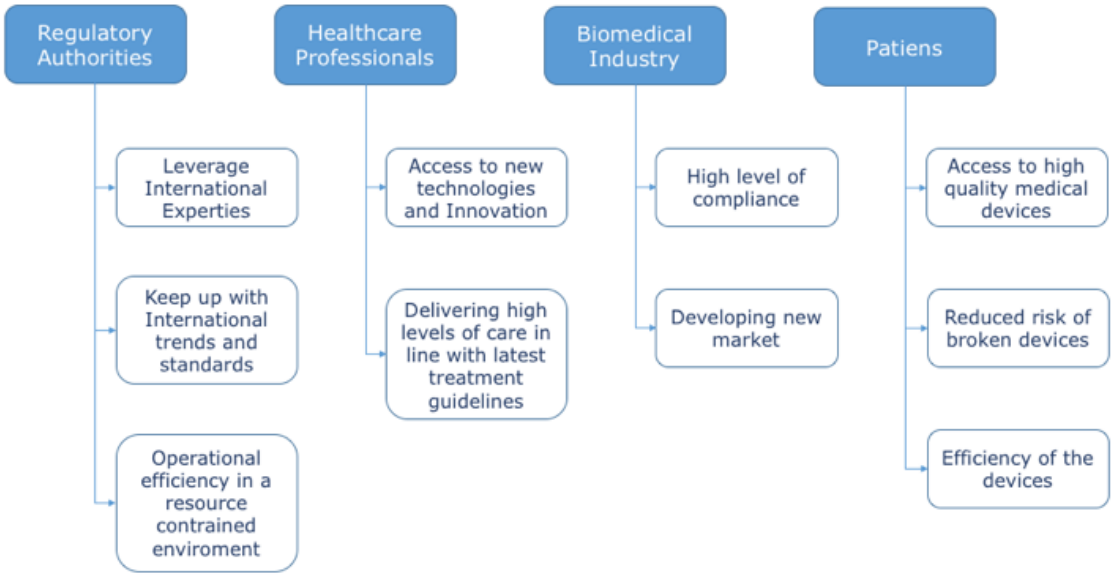

Figure 6.1: Benefits of standards harmonisation

Africa need such innovation support infrastructure to encourage and foster innovation. Industry can sponsor the labs or the ideas developed within the labs or assist in staffing these labs. This would expose students to the needs and ethos of industry and create the opportunity to integrate future employers (industry) with academia. The infrastructure for innovation may include online knowledge exchange and open innovation platforms. Such platforms enable creative individuals to post exciting challenge solutions as well as sharing of new technologies. These may include free design software packages that can be downloaded and used to create and develop innovations. To use these effectively, there must be a affordable and reliable internet access and information technology support units in institutions in Africa. This remains a significant challenge as costs of internet usage may be high and the service slow and unreliable.

For this reason the UBORA's goal to develop an Europa-Africa e-infrastructure for open-source co-design technologies of new solutions to face the current and future healthcare challenges of both continents, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance, can be a solution to improve the healthcare in Africa through Biomedical Engineering.

The UBORA e-platform has the objective of gathering partner universities as well as industrial and regulatory experts to support and evaluate the documentation and design of African medical devices. This platform enables a peer-to-peer

evaluation before submitting the documentation to a Notified Body. This double check of the design might then lead to safer medical products because a large community as well as a regulatory authority are performing the evaluation. This platform is conceived as a facility for creating open excellence and innovation in Biomedical Engineering, comprising an array of design resources, including blueprints and performance data. It is an integrated virtual ecosystem which will lead engineers and healthcare workers through all the phases of innovative design, fabrication, development, testing and implementation of biomedical technology.

It has been thought that the platform will be composed of four sections, show in Figure 6.2.

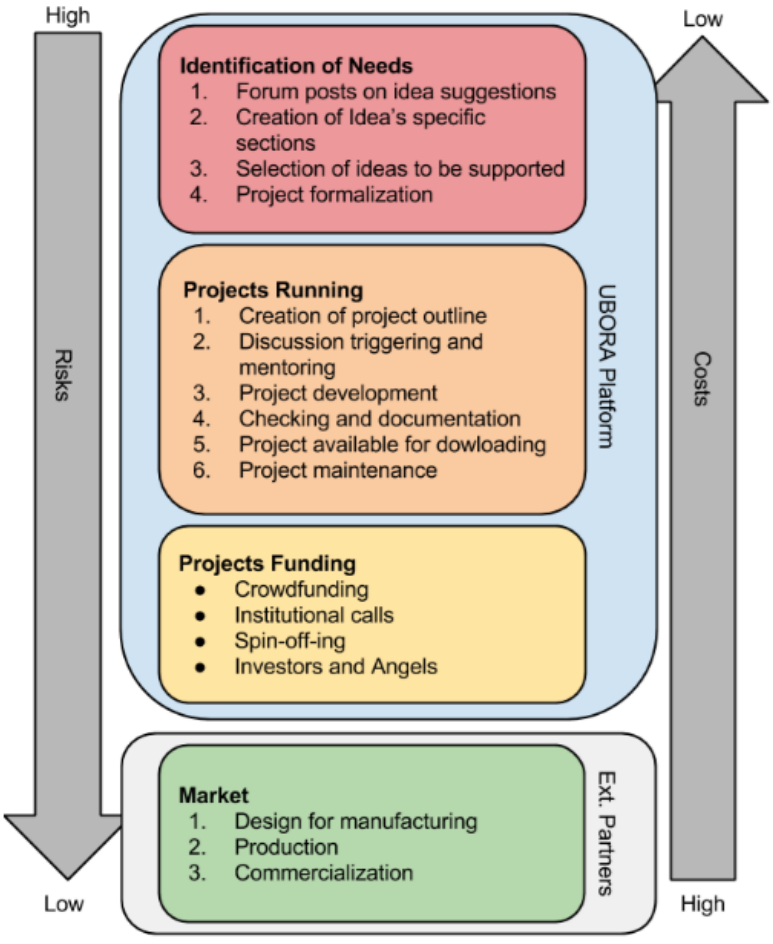

Figure 6.2: Device development through e-platform

Specific objectives of the e-platform are:

- a web-based platform of biomedical devices;

- to generate and upload a complete set of open-source projects with data on performance and safety;
- to empower innovation in healthcare, sustained by a good academic background in BME.

The e-Infrastructure will be aimed at stimulating innovation in the field of BME through knowledge distribution, promoting harmonization of biomedical device requirements, design and manufacturing, with subsequent impacts on healthcare services and ultimately on patient safety. Furthermore, it will give the possibility to both Europe and Africa to develop the capacities to create and exploit new technologies. These capacities will give the possibility to economic growth, health, a better environment and the creation of jobs in both continents. Quality and safety guidelines for biomedical device standards will be established and then spread to other institutions through partnerships and linkages embedded in the platform's architecture. Key to the coordination efforts is the multilevel approach to dissemination and networking, involving students, technicians, NGOs, universities, regulatory bodies, and policy makers. Through design competitions, UNECA inspired to Summer Schools, it will be possible to improve the platform and disseminate the initiative.

6.3 Building the human capital base

One of the main challenge facing the development of the health sector and medical devices industry in Africa is the limited qualified and experiences human capital. The rapid growth in university education has not automatically and proportionally translated in the development of specialized programmes. Building technical engineering capacity of the local workforce within developing countries to empower local technicians, engineers and other personnel to be able to maintain and handle their own equipment has been evaluate as a possible approach to improve the healthcare in Africa because a strong competent technological foundation is the basis for the research and innovation. Figure 6.3 shows the improve of capacities during the time.

It is necessary to create programs that bring together government efforts, academia, and industry to increase the pool of qualified and readily employable professionals and technicians. A mix of programs is necessary to Biomedical technicians and engineers.

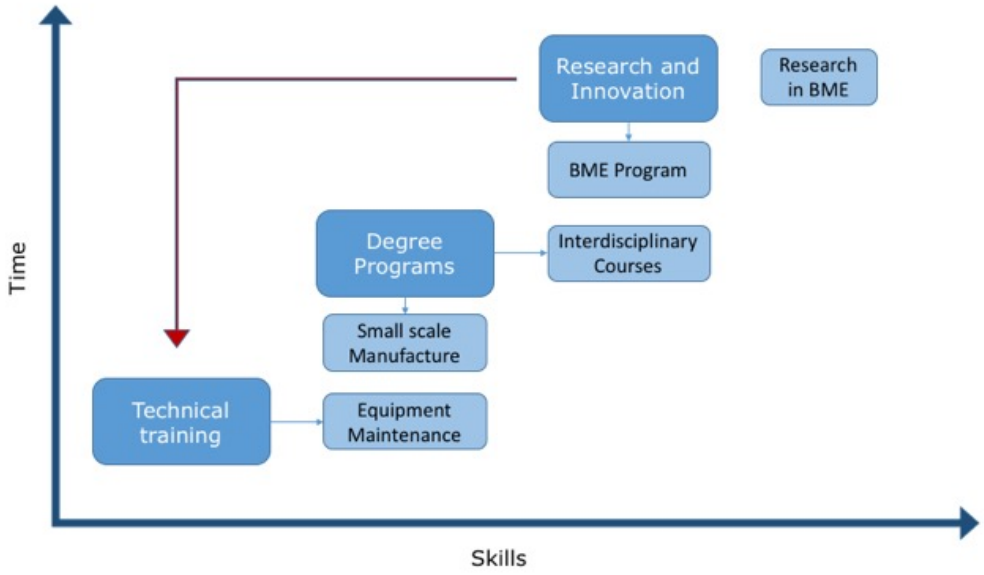

Figure 6.3: Biomedical Engineering capacity building

6.3.1 Training for Biomedical Engineering Degree

The UNECA-led initiatives has demonstrated that interest among students and universities in biomedical engineering programme is high. University level biomedical engineering programmes are not necessarily designed to train technical staff but rather supervisors and managers for hospitals and public institutions, and researchers and innovators for the industry. The first is important as decisions on procurement is made in boardrooms of hospitals and ministries. For most of the large hospitals, the leadership hierarchy does not include technicians in management teams and errors on orders often escape. The second matters in ensuring Africa participates in the rapidly growing and evolving industry by ensuring a supply of researchers and innovators. In any case, the technology used in some of the medical devices (e.g. software, sensors etc) does not radically differ from that used in other industries. Interested African universities should be supported to overcome a number of challenges that affect the effective delivery of BME programmes. Support may include provision of scholarships and funding to enable university increase the numbers of lecturers with qualifications in BME and acquire basic laboratories for training biomedical engineers and other facilities for design and rapid prototyping, technology transfer offices and incubators. These will enable universities to training biomedical engineers that are inspired to identify and realise innovation opportunities. Figure 6.3 shows the impacts of Biomedical Engineering Degree students training during the time.

6.3.2 Training for Biomedical Engineering Diploma

The graduates of the biomedical engineering diploma found many benefits with the involvement of Amalthea Trust in the training. The students fell that the exposure to different equipment, technicians and engineers from the UK has left them with the skills and support to deal with a number of biomedical engineering related problems.

In agreement with the graduates, the trainers highlighted the benefits of the UK engineers training and engaging with the students. However, they too point to some challenges similar to those identified by the students. They identified the major challenge to be limited opportunities for visiting hospitals and short internship duration for students. They also recognise the need to train or support training of local trainers through properly accredited programmes. One of the trainers thought that the graduates would be greatly helped if the hospital managers and administration received training in equipment management. The technicians find much resistance when trying to convince the management to invest in all the different aspects of equipment management apart from repairs. This was identified as one of the areas that Amalthea Trust could look into providing support.

It was also pointed out that it would be important for the new trainees to be mentored by the graduates. This way they can share their experiences, especially challenges of working in healthcare facilities in Uganda.

The lack of a platform to share knowledge and experiences was identified as one of the areas that needed improvement. Though they pointed to a website, an organisation such as Amalthea Trust would be suitable in providing a platform to address the issues of mentorship, sharing of experience as well as support and guidance for the technicians in the field in the country. Through organising seminars, workshops and conferences on dedicated topics, the field of Biomedical Engineering would be greatly improved. Being new in the country, the field needs to be sold to many stakeholders so that it can receive sufficient support and approval to benefit the healthcare system of the country. Figure 6.3 shows the impacts of Biomedical Engineering Degree technicians training during the time.

6.4 Regulation on donated medical device

If about 40% of donated medical equipment is out of service, does a donation strengthen the health system?

The answer probably depends on the specific piece that is being donated. The

amount of out of service equipment does not depend strongly on the type of equipment. We can conclude that about 40% of donated X-ray machines and about 40% of donated pulse-oximeters do not work. However, a given donation may provide 100 pulse-oximeters while only providing one X-ray machine. In this case, the donation of pulse-oximeters undoubtedly would help. However, there is about a 40% chance that the X-ray equipment donation would not.

A commonly cause for equipment being considered out of service is the lack of spare parts and disposable accessories [98] [99] [21]. However, in one of the very few prospective studies Robert Malkin, a professor of the practice of biomedical engineering at Duke University, showed that 66% of out of service equipment could be returned to service using only locally available materials and less than $50. This suggests that there may be a predisposition to designating a piece of equipment as being out-of-service. Or, this could indicate that the higher level of training of most of the volunteers in the Malkin and Keane study allowed for more repairs [100].

While the vast majority of donations are given with the genuine intent to strengthen the health system, probably a large percentage did not consider the technical infrastructure of the receiving hospital. Medical equipment is designed to operate where there is stable electricity and sophisticated amenities such as purified water or pressurized gas, such infrastructure is rare [98]. Drastic environmental changes also pose a challenge to operation and maintenance of modern, delicate equipment [99]. Even American hospitals often rely on medical service contracts to keep their equipment running. From the analysis, it is apparent that many organizations, even those donating new equipment, are doing so without donating a service contract [98] [101]. In many cases, a donation without a service contract very quickly leaves the hospital with an inoperative piece of equipment and a disposal problem. In other words, the donation leaves the hospital worse off, see Figure 6.4

The most important prerequisite for a successful donation is that the potential recipient truly needs the requested equipment and has the expertise and the means to operate and maintain it. The donor should use this criterion to identify potential recipients. A donation plan is required, and should cover all items in the accompanying checklist, notably availability of trained personnel for operation and maintenance, and support for other resources for operation (manuals, reagents, supplies, etc.) and maintenance (technical documentation, spare parts, etc.).

The donated equipment should meet general criteria covering quality of the

Figure 6.4: A dumping ground for old medical equipment in Malawi

equipment, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the technology for the user environment. In addition, donation plans must include detailed installation and commissioning procedures. Finally, any special requirements for the equipment such as, air or water cooling, electrical power, water quality, mechanical lay-out or radiation or acoustic shielding requirements, specialized software required to install, operate, or maintain the equipment, should be communicated to the recipient. The recipient should develop a plan for proper management of the donated equipment, covering site preparation for commissioning and installation, and training of both users and maintenance staff.

Donations often involve equipment removed from service in health care facilities in industrialized countries. However careful economic analysis should be done of both new and used equipment options, taking into account payment conditions and other financing mechanisms, leasing and rental options, reagent contracts, safety and performance criteria, as well as continued availability of spare parts. Refurbishers of medical devices must be competent, and are expected to restore equipment to the manufacturer's original specifications, provide complete documentation and properly label equipment.

Donations can cause problems and there are undoubtedly some hospitals where the situation is much worse, but in the end the analysis suggests that donating equipment can improve the available healthcare options. Better communication between a donor and the recipient country can help ensure that the medical equipment is appropriate to the setting, safe, cost effective and easy to maintain. On the other hand, investments in capacity building, health technology man-

agement and infrastructure could nearly double the amount of working medical equipment without the expense of collecting, testing, and shipping used medical devices.

Conclusions

The research reported in this thesis is focused on four different approaches useful to improve the healthcare in Africa through biomedical engineering.

As explained during the thesis, European Directives for medical device regulations are quite strict and time-consuming, but also essential in order to protect safety and health of each individual. This research showed that African medical device regulations have an affinity to European directives. It was observed that all ABEC countries already have a National Regulatory Authority in place, to control and regulate medical devices. The majority of those states also implemented or harmonized directives to medical device regulation, while other countries, which do not have a significant number of regulations, have a huge interest to establish them in their legislation to provide access to safe, effective and quality medical products. However, due to limited human capacities in Biomedical Engineering, most of the African countries cannot regulate medical devices properly. A paper on this analysis has been completed and published in the 38th Annual International Conference of the Engineering in Medicine and Biology Society (EMBC), IEEE on October 18, 2016.

An other issue highlighted during the thesis was high cost of medical devices. The Open Source design has been shown as possible solution, because it offers a unique combination of advantages: reducing costs and faster innovation. Two manufactured devices have been presented with a step-by-step description; it could be useful to enable also people scarcely educated in engineering principles, to create cheaper and commonly used medical devices, fabricated to meet their needs.

The IR Thermometer bluetooth, connected with an Android phone, had the purpose to show to students from 13 African universities the application of mobile phone in the design of medical devices, which was the topic of the ISS 2016 in Ethiopia.

The 3D-printed Spectacles instead have been manufactured with an automatized system that requires the insertion of few data to design customized specta-

cles. The goal is to give the opportunity to anyone, through Open Source design system, to fabricate tailored spectacles by simply changing a few parameters into a script, for taking into account anatomic dimensions, as well as refractive errors of the patients. Numerous enhancements on transparency of lenses have been conducted though there is still space for further improvements.

These devices were useful also to demonstrate that the aim of UBORA to develop an Europe-Africa e-infrastructure for Open Source co-design technologies which could be a new solution to face the current and future healthcare challenges of both continents, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance.

The student's capacity building through the experience of ISS in Addis Ababa, considering also the survey's results, has been evaluated positively during the thesis work, and its success is due in particular to the stimuli of a practical approach in BME.

The technicians's capacity building as properly proved during this work is also fundamental to improve the healthcare in Africa, due to the fact that most medical devices are imported and most of them are not put into operation. The experience with Amalthea Trust in training biomedical engineering technicians at Kyambogo University was positive for stimulating practical approach in repairing, in particular Ultrasound machine and X-ray machine. The visits to Mengo Hospital in Kampala, and Mbale Referral Hospital, where it was possible to see in detail the orthopaedic outpatients department, artificial limb construction, physiotherapy, dental, and pathology departments, was of great interest for students.

During the experiences in Africa the interviews of 20 questions to 60 people with different background (as students, physicians, lectures and technicians) were useful to evaluate their needs, and to understand what they think and what they want from their education in BME. The interviewers, and in particular technicians students do not have a good opinion about the donated medical devices, and justify their thought underlining a lack of regulation: a lack of a proper planning of assistance, as well as a supply contract for spare parts, and lacks of handbooks.

The possibility to visit three different hospitals, and to see directly the conditions of donated equipments has given to me the possibility to write a report of my findings. Donations can cause problems, and there are undoubtedly some hospitals where the situation is much worse, but in the end the analysis suggests that donating equipment can improve the available healthcare options. Better communication between the donor and the recipient country can ensure that the

medical equipment is: appropriate to the setting, safe, cost effective, and easy to maintain: for these reasons a properly regulation on donated medical devices is essential.

In conclusion, it is necessary to underline that putting in practice a single approach does not involve significant improvements on the healthcare in Africa; whilst a combined approach of the strategies described above can have positive impacts. Thereby, it is imperative to find a solution that harmonizes all the approaches, in order to advance towards a sustainable healthcare system for African countries.

Appendices

APPENDIX A

Atlas of Medical devices

Egypt

Country indicators

Population (000s)[α]	82'056	Life expectancy at birth (years)[α]	71	World Bank income group[β]	Lower-middle
Internet users (%)[γ]	49.6%	Per capita total health expenditure (PPP Int $)[δ]	323	GNI per capita (US$)[ε]	3'140

National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy
Web site: http://10.0.0.115/mohweb/login.aspx
Language(s): Arabic and English
MOH responsible for health technology policy implementation: There Administration medical devices, but not available with limited hardware, but is limited to the knowledge of the geographical unit of health information GIS Aantrz National Health Information

Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: —
Name of principal institution: —
Web site: http://www.eda.mohp.gov.eg/Services/Reg_MedDevice.aspx?Main=Services&Serviceid=2&Submain=serv8
Contact: —
Telephone number: —
Email: —

National health technology assessment unit

Unit/department: The management of hospitals
Web site: www.mohealth.gov.eg
Contact: —
Email: —

National health technology management units

National health technology unit(s): Yes

DEVELOPMENT OF TECHNICAL SPECIFICATIONS FOR PROCUREMENT PROCESS:
Unit/department: Department of Radiology
Web site: www.mohealth.gov.eg
Contact: —
E mail: —

OTHER: HTA/Application/user training
Unit/department: Quality Management
Web site: —
Contact: —
Email: —

OTHER: Development of technical specifications for procurement purposes/application/training
Unit/department: Management of medical devices
Web site: www.mohealth.gov.eg
Contact: —
Email: —

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified
Nomenclature system name: Database of geographical information system health Web site: http://10.0.0.115/MOHWeb/Default2.aspx

Medical device incorporation

PROCUREMENT
Policy or guideline: Yes
Web site: —
National level procurement: Yes
Web site: —

DONATIONS
Policy or guideline: Yes
Web site:—

TECHNICAL SPECIFICATIONS
Technical specifications to support procurement or donations: Yes
Web site: —

Medical device incorporation comments[λ]:
Management of medical equipment and hospital management. Curative medicine sector and management of medical devices

World Health Organization
http://www.who.int/medical_devices

Inventory and maintenance

Type of inventories available: National inventory for medical equipment

Comments: —

Medical equipment management unit: Yes

Management software: Yes

National level = —	Regional level = —	Hospital level = —

Software and comments[λ]: Database of geographical information system health

Lists of medical devices

Lists of approved medical devices for public procurement or reimbursement:

Lists available: No

Unit: —

Web site: —

Lists comments[λ]:
Concerning lists of healthcare facilites, they were counted by the sector ministry and therapeutic medicine National Information Center Ministry

National lists of medical devices for different types of healthcare facilities or specific procedures: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: —

Web site - procedures: www.mohealth.gov.eg

National list for diseases and situations:

Lists available: One or more

Web site: http://www.mohealth.gov.eg

Types:	Communicable diseases	x	Non-communicable diseases		Injuries	x	Public health emergency situations	

Healthcare facility

Healthcare facility	Public sector	Private sector	Total	Density per 100,000 population
Health post	314	n/a	314	0.383
Health centre	208	n/a	208	0.253
District hospital	407	n/a	407	0.496
Provincial hospital	n/a	n/a	n/a	n/a
Regional hospital	99	n/a	99	0.121

Medical equipment

Medical equipment	Public sector	Private sector	Total	Density per 1,000,000 population
Magnetic Resonance Imaging	n/a	n/a	n/a	n/a
Computerized Tomography Scanner	n/a	n/a	n/a	n/a
Positron Emission Tomography Scanner	n/a	n/a	n/a	n/a
Nuclear medicine	n/a	n/a	n/a	n/a
Mammograph*	n/a	n/a	n/a	n/a
Linear accelerator	n/a	n/a	n/a	n/a
Telecobalt unit (Cobalt-60)	n/a	n/a	n/a	n/a
Radiotherapy	n/a	n/a	n/a	n/a

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments[λ]:

Concerning Infrastructure Section: The proposed names are not totally compatible with ours. Thus the number of units is under the Ministry of Health only and is not confined to Tfsalia to the private sector in 2010.

Contacts

Focal point

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WHO representive:

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Email: Bekedamh@who.int

WHO health products focal point:

Name: Dr Sohier Saad Botrous Attalla

Email: ssb_attalla@yahoo.com

Telephone: (+20) 1222557330

* UNPD as of 1 July 2012 (2013 update)
α WHO 2012 data
β WB 2014 classification
γ WB 2013 data (2014 update)
δ WHO 2012 data
ε WB 2013 (2014 update)
n/a not applicable
λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

World Health Organization
http://www.who.int/medical_devices

Ethiopia

Country indicators

Population (000s)*	94'101	Life expectancy at birth (years)α	64	World Bank income groupβ	Low
Internet users (%)γ	1.9%	Per capita total health expenditure (PPP Int $)δ	44	GNI per capita (US$)ε	470

National policy on health technology

Health technology (medical device) national policy: No
Web site: —
Language(s): —
MOH responsible for health technology policy implementation: Food Medicin and Hygine administrahion Control Agency

Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes
Name of principal institution: Food, medical & health Administration and Control Authority
Web site: www.fmhaca.gov.et
Contact: —
Telephone number: —
Email: —

National health technology assessment unit

Unit/department: Public Health Infrastructure Directorate
Web site: http://www.moh.gov.et
Contact: Mekonnen Engida
Email: mekonen_engda@yahoo.com

National health technology management units

National health technology unit(s): Yes

Development of technical specifications for procurement process:
Unit/department: Public Health Infrastructure Directorate
Web site: http://www.moh.gov.et/
Contact: Mekonnen Engida
E mail: mekonen_engda@yahoo.com

Other: Planning for conduct medical equipment inventory at hospital level/application/user training
Unit/department: Public Health Infrastructure Directorate
Web site: http://www.moh.gov.et/
Contact: Mekonnen Engida
Email: mekonen_engda@yahoo.com

Other: Planning of medical equipment allocation
Unit/department: Public Health Infrastructure Directorate
Web site: www.moh.gov.et/
Contact: Mekonnen Engida
Email: mekonen_engda@yahoo.com

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: For procurement
Nomenclature system name: — Web site: www.fmhaca.gov.et

Medical device incorporation

Procurement
Policy or guideline: Yes
Web site: www.fmoh.gov.et
National level procurement: Yes
Web site: —

Donations
Policy or guideline: Yes
Web site:www.fmhaca.gov.et

Technical specifications
Technical specifications to support procurement or donations: Yes, but not publically available
Web site: www.pfsa.gov.et

Medical device incorporation commentsλ:
—

World Health Organization
http://www.who.int/medical_devices

Inventory and maintenance

Type of inventories available: None

Comments: AAU, Tikur Anbesa specialized Hospital update medical Inventory & Equipment history file in 2013

Medical equipment management unit: Yes

Management software: Yes

Software and comments[λ]: HARVEST Dimo

National level = 2	Regional level = 0	Hospital level = 0

Lists of medical devices

Lists of approved medical devices for public procurement or reimbursement:

Lists available: Yes

Unit: Pharmactical Fund & Supply Agency

Web site: –

Lists comments[λ]:
Actually there is a revision for national lists.

National lists of medical devices for different types of healthcare facilities or specific procedures: Lists available: For different healthcare facilities and specific procedures

Web site - facilities: –

Web site - procedures: www.fmhaca.gov.et

National list for diseases and situations:

Lists available: One or more

Web site: www.fmhaca.gov.et

Types: Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations

Healthcare facility

Healthcare facility	Public sector	Private sector	Total	Density per 100,000 population
Health post	14'250	n/a	14250	15.143
Health centre	2	n/a	1.75	0.002
District hospital	181	n/a	181	0.192
Provincial hospital	n/a	n/a	n/a	n/a
Regional hospital	6	19	25	0.027

Medical equipment

Medical equipment	Public sector	Private sector	Total	Density per 1,000,000 population
Magnetic Resonance Imaging	2	5	7	0.074
Computerized Tomography Scanner	12	22	34	0.361
Positron Emission Tomography Scanner	0	0	0	0.000
Nuclear medicine	1	0	1	0.011
Mammograph*	n/a	n/a	n/a	n/a
Linear accelerator	0	0	0	0.000
Telecobalt unit (Cobalt-60)	2	0	2	0.021
Radiotherapy	2	0	2	0.021

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments[λ]:

Concerning HT nactional policy we provide the following doc.: National Health Policy.pdf
Concerning Infrastructure section: The targets of the government are to expand the current infrastructure capacity.

Contacts

Focal point

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WHO health products focal point:

Name: Mideksa Mulugeta

Email: mulugetamideksa@yahoo.com

Telephone: –

* UNPD as of 1 July 2012 (2013 update)
α WHO 2012 data
β WB 2014 classification
γ WB 2013 data (2014 update)
δ WHO 2012 data
ε WB 2013 (2014 update)
n/a not applicable
λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

World Health Organization
http://www.who.int/medical_devices

Uganda

Country indicators

Population (000s)*	37'579	Life expectancy at birth (years)α	57	World Bank income groupβ	Low
Internet users (%)γ	16.2%	Per capita total health expenditure (PPP Int $)δ	108	GNI per capita (US$)ε	550

National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy
Web site: —
Language(s): English
MOH responsible for health technology policy implementation: HEALTH INFRASTRUCTURE DIVISION

Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes
Name of principal institution: NATIONAL DRUG AUTHORITY
Web site: http://www.nda.or.ug
Contact: Gordon K Sematiko
Telephone number: (+25) 6414344052 or (+25) 6776110008
Email: ndaug@nda.or.ug

National health technology assessment unit

Unit/department: —
Web site: —
Contact: —
Email: —

National health technology management units

National health technology unit(s): Yes

Development of technical specifications for procurement process:
Unit/department: Health Infrastructure division
Web site: http://www.health.go.ug
Contact: Eng. John Tumwesigye
E mail: tumwesigyejk@gmail.com

Other: Planning of medical equipment allocation/Technical Specifications/Application/ user training
Unit/department: Health Infrastructure division
Web site: http://www.health.go.ug
Contact: Eng. Sitra Mulepo
Email: sitraik@hotmail.com

Other: Technical specifications/application/user training
Unit/department: National advisory committee on medical equipment
Web site: http://www.health.go.ug
Contact: Dr. Edward Naddumba
Email: edwardnaddumba@yahoo.com

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed Use: Not specified
Nomenclature system name: List of medical equipment by level. Web site: —

Medical device incorporation

Procurement
Policy or guideline: Yes
Web site: —
National level procurement: Yes
Web site: http://www.health.go.ug

Donations
Policy or guideline: Yes
Web site:http://www.health.go.ug

Technical specifications
Technical specifications to support procurement or donations: Yes, but not publically available
Web site: —

Medical device incorporation commentsλ:

The ministry acquires resources and procures in bulk although for the last 2 years development funds for infrastructure have been directly allocated to regional refferal hospitals who procure equipment with guidance of the health infrastructure division and national advisory committee on medical equipment (NACME).

World Health Organization
http://www.who.int/medical_devices

Inventory and maintenance

Type of inventories available: National functional inventory for medical equipment
Comments: Currently being updated
Medical equipment management unit: Yes
Management software: No
Software and comments[λ]: –

National level = 1	Regional level = 8	Hospital level = 1

Lists of medical devices

Lists of approved medical devices for public procurement or reimbursement:
Lists available: Yes
Unit: NATIONAL ADVISORY COMMITTEE ON MEDICAL EQUIPMENT (NACME)
Web site: –

National lists of medical devices for different types of healthcare facilities or specific procedures: Lists available: For different healthcare facilities
Web site - facilities: –
Web site - procedures: –

National list for diseases and situations:
Lists available: No list available
Web site: –

Types: Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations

Lists comments[λ]:
Not aware of any standards or lists for specific procedures, neither lists for communicable and non communicable diseases, injuries, and public health emergency situations. Usually we use WHO recommendations. List of equipment by health care level was already given.

Healthcare facility	Public sector	Private sector	Total	Density per 100,000 population
Health post	1'696	1'909	3605	9.593
Health centre	1'107	365	1472	3.917
District hospital	48	88	136	0.362
Provincial hospital	14	n/a	14	0.037
Regional hospital	2	n/a	2	0.005

Medical equipment	Public sector	Private sector	Total	Density per 1,000,000 population
Magnetic Resonance Imaging	0	3	3	0.080
Computerized Tomography Scanner	2	15	17	0.452
Positron Emission Tomography Scanner	0	0	0	0.000
Nuclear medicine	1	1	2	0.053
Mammograph*	3	2	5	4.411
Linear accelerator	0	0	0	0.000
Telecobalt unit (Cobalt-60)	1	1	2	0.053
Radiotherapy	1	1	2	0.053

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments[λ]:

The policy guidelines on donations is at Chapter Chapter 5.1.5 of the medical equipment policy (see documentations)

Contacts

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* UNPD as of 1 July 2012 (2013 update)
α WHO 2012 data
β WB 2014 classification
γ WB 2013 data (2014 update)
δ WHO 2012 data
ε WB 2013 (2014 update)
n/a not applicable
λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

World Health Organization
http://www.who.int/medical_devices

South Africa

Country indicators

Population (000s)*	52'776	Life expectancy at birth (years)α	59	World Bank income groupβ	Upper-middle
Internet users (%)γ	48.9%	Per capita total health expenditure (PPP Int $)δ	982	GNI per capita (US$)ε	7'190

National policy on health technology

Health technology (medical device) national policy: Yes, and it is part of the National Health Program/Plan or Policy
Web site: —
Language(s): English
MOH responsible for health technology policy implementation: Health Technology Directorate

Regulatory agency

Authority responsible for implementing and enforcing regulations in your country: Yes
Name of principal institution: Directorate: Radiation Control
Web site: http://www.doh.gov.za/show.php?id=2961
Contact: Seppie Olivier
Telephone number: (+27) 21 948 6162
Email: olives@health.gov.za

National health technology assessment unit

Unit/department: HTWC
Web site: —
Contact: Mr. H. Radyn
Email: hjradyn@pgwc.gov.za

National health technology management units

National health technology unit(s): Yes

Development of technical specifications for procurement process:
Unit/department: HTKZN
Web site: —
Contact: Mr Thami Mhlongo
E mail: Thami.Mhlongo@kznhealth.gov.za

Other: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training
Unit/department: HTFS
Web site: —
Contact: Mr S. du Plessis
Email: duples@fshealth.gov.za

Other: Planning of medical equipment allocation/HTA/development of technical specifications/application/user training
Unit/department: HTWC
Web site: —
Contact: Mr H Radyn
Email: hjradyn@pgwc.gov.za

Medical device nomenclature system

Official nomenclature system for medical devices: No Type: None Use: No
Nomenclature system name: — Web site: —

Medical device incorporation

Medical device incorporation commentsλ:
—

Procurement
Policy or guideline: No
Web site: http://www.treasury.gov.za/legislation/pfma/Default.aspx
National level procurement: No
Web site: —

Donations
Policy or guideline: Yes
Web site:—

Technical specifications
Technical specifications to support procurement or donations: Yes, but not publically available

World Health Organization
http://www.who.int/medical_devices

Web site: –

Inventory and maintenance

Type of inventories available: None

Comments: No National inventory but some hospitals do have. We are currently compiling a national inventory.

Medical equipment management unit: Yes

National level = 1	Regional level = 8	Hospital level = 18

Management software: Yes

Software and comments[λ]: But No National system. Different systems used in different hospitals. Currently acquiring a system to be implemented nationally

Lists of medical devices

Lists of approved medical devices for public procurement or reimbursement:

Lists available: Yes

Unit: –

Web site: –

National lists of medical devices for different types of healthcare facilities or specific procedures: Lists available: For different healthcare facilities

Web site - facilities: –

Web site - procedures: –

National list for diseases and situations:

Lists available: No list available

Web site: –

Types: Communicable diseases | Non-communicable diseases | Injuries | Public health emergency situations

Lists comments[λ]:

We don't have any lists of the mentioned above. The list is only for the private sector funders (not government). National Dept of Healt is engaging with private sector to establish a national system.

Healthcare facility	Public sector	Private sector	Total	Density per 100,000 population
Health post	3'105	n/a	3105	5.883
Health centre	289	n/a	289	0.548
District hospital	279	n/a	279	0.529
Provincial hospital	63	n/a	63	0.119
Regional hospital	14	n/a	14	0.027

Medical equipment	Public sector	Private sector	Total	Density per 1,000,000 population
Magnetic Resonance Imaging	12	n/a	12	0.227
Computerized Tomography Scanner	51	n/a	51	0.966
Positron Emission Tomography Scanner	3	n/a	3	0.057
Nuclear medicine	28	n/a	28	0.531
Mammograph*	32	n/a	32	7.777
Linear accelerator	21	n/a	21	0.398
Telecobalt unit (Cobalt-60)	9	n/a	9	0.171
Radiotherapy	30	n/a	30	0.568

* Density per 1,000,000 females aged from 50-69 old.

Additional information and comments[λ]:

–

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* UNPD as of 1 July 2012 (2013 update)
α WHO 2012 data
β WB 2014 classification
γ WB 2013 data (2014 update)
δ WHO 2012 data
ε WB 2013 (2014 update)
n/a not applicable
λ The full text can be found at www.who.int/medical_devices/countries/full_text.xls

World Health Organization
http://www.who.int/medical_devices

APPENDIX B

Essential Principle of safety and Performance of Medical Device

Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this guidance document that has been developed to encourage and support global convergence of regulatory systems [102].

Essential Principles - General requirements

1. Medical devices designed and manufactured so that when used as recommended, does not compromise safety, and acceptable risks compared to benefits to the patient.

2. Design and manufacture of the devices should conform to safety principles and risk reduction measures taken as follows:

   - Known/foreseeable hazards identified and associated risks arising from intended use and foreseeable misuse estimated.
   - Risks eliminated as far as possible through inherently safe design and manufacture.
   - Remaining risks reduced as far as possible by taking adequate protection measures, including alarms.
   - Residual risks informed to users.

3. Devices achieve intended performance, and designed, manufactured and packaged to suit one or more listed functions.

4. Characteristics and performances will not adversely affect health or safety of the patient/user/other persons during the lifetime of the device, when

subjected to normal stresses of use and maintained as recommended.

5. Characteristics and performances of device not adversely affected by transport and storage conditions.

6. Clinical evidence demonstrating compliance to essential principles, appropriate class of device and for the use is available.

Essential Principles – Design and Manufacturing Requirement

Designed and manufactured to ensure the following:

1. The characteristics and performance referred above, especially focusing on the following:

   - Use of non-toxic and non-flammable (where applicable) materials.
   - Materials used compatible with biological tissues, body fluids, and specimens, depending on intended use of the device.
   - Materials used should have resilience wear and fatigue strength appropriate for use of the device.

2. Minimize risk of contamination and residues of patients and those involved in transport, storage and use, depending on intended use of the device, especially where tissues are exposed.

3. - Safe use with materials, substances and gases coming into contact with devices during normal use or during routine procedures.
   - Be compatible with relevant drugs for devices intended to administer these drugs and performance is maintained in accordance with the intended use.

4. Ensure safety and performance of combination devices including the connection system, of devices used in combination with other devices. Removing or reducing as far as reasonably practicable and appropriate:

   - Risk of injury from physical features e.g. volume/pressure ratio, dimensions, ergonomic features etc.
   - Risks from external influences/environmental conditions e.g. magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature, variations in pressure etc.

- Risks when used with materials, substances and gases with which they may come into contact during normal conditions of use.
- Risks of accidental penetration of substances into the device.
- Risk of incorrect identification of specimens.
- Risks of reciprocal interference with other devices normally used in the investigations or for the treatment given.
- Risks from ageing of materials used or loss of accuracy of any measuring or control mechanism, due to maintenance/calibration not being possible e.g. implants.
- Risk of exposure of patients, users and other persons to any emitted radiation, compatible with the intended use, but not restricting the application for therapeutic and diagnostic purposes
- Risk of exposure of patients, users and other persons to any emission of unintended, stray or scattered radiation.
- Risks of creating electromagnetic interference which could impair the operation of this or other devices in the usual environment.
- Risks arising from vibration generated by the device, unless the vibrations are part of the specified performance.
- Risks arising from the noise emitted by the device, unless the noise emitted is part of the specified performance.
- Risk of use error in the handling of the device and, if applicable, the specimen, and also in the interpretation of results.

5. Minimizing risks of fire/explosion during normal use and in single fault condition, especially in devices exposed to or used with inflammable substances.

6. Facilitating the safe disposal of any waste substances.

7. Providing sufficient accuracy, precision and stability:

    - Based on appropriate scientific and technical methods for devices with a measuring function, where inaccuracy could adversely affect the patient.
    - Sensitivity, specificity, repeatability, reproducibility, control of known relevant interference and limits of detection should be addressed.

8. Assuring traceability of values assigned to calibrators and/or control materials using a quality management system for devices whose performance depends on these.

9. Designing measurement, monitoring or display scales ergonomically based on the intended purpose of the device.

10. Enabling users to control and vary the quantity, geometry and energy distribution (or quality) of radiation emitted of devices designed to emit hazardous/ potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose and fitted with visual displays and/or audible warnings of such emissions

11. Enabling appropriate image and/or output quality for the intended medical purpose to be achieved but minimizing radiation exposure of the patient and user of devices emitting ionizing radiation intended for diagnostic radiology.

12. Enabling reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam of devices emitting ionizing radiation, intended for therapeutic radiology.

13. Ensuring repeatability, reliability and performance of devices incorporating electronic programmable systems, including software according to use.

14. Ensuring safety of patients by providing means of determining the state of the power supply of devices depending on an internal power supply.

15. Ensuring safety of patients by providing an alarm system to signal any power failure of devices depending on an external power supply.

16. Ensuring safety of patients by providing appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health in devices monitoring one or more clinical parameters.

17. Verifying the safety, quality and usefulness of the drug for devices incorporating a drug, depending on the intended use of the device.

18. Reducing risks posed by substances that may leach or leak from the device as far as possible and appropriate depending on the intended use of the device.

19. Reducing risks posed by the unintentional entry or outpouring of substances into or from the device as far as possible and appropriate depending on the intended use of the device and the environment where it is intended to be used.

20. Eliminating or reducing the risk of infection to patients, users and other persons as far as possible and appropriate by focusing on the following:

    - Allowing easy handling.
    - Reducing microbial leakage and/or microbial exposure from the device as far as possible and appropriate during use.
    - Preventing microbial contamination of the device or specimen, by the patient, user or other person.

21. Reducing the risk of infection as far as possible and appropriate in devices incorporating substances of biological origin, by selection of appropriate sources, donors and substances and by effective control measures.

22. providing optimal safety from viruses and other transmissible agents in devices incorporating animal tissues and substances of animal origin by the following:

    - tissues should be from animals subjected to veterinary controls and surveillance,
    - implementing validated methods to eliminate or inactivate viruses and other transmissible agents in the manufacturing process.

23. providing optimal safety from viruses and other transmissible agents in devices incorporating tissues and derivatives of microbial or recombinant origin by the following:

    - To provide optimal safety in selection of sources/donors, processing, preservation, testing and handling of cells, tissues and derivatives.
    - Implementing validated methods to eliminate or inactivate viruses and other transmissible agents in the manufacturing process.

24. providing optimal safety from viruses and other transmissible agents by their elimination or inactivation in devices incorporating non-viable human tissues and substances by the following:

- to provide optimal safety in selection of sources/donors, processing, preservation, testing and handling of cells, tissues and derivatives
- Implementing validated methods to eliminate or inactivate viruses and other transmissible agents in the manufacturing process.

25. Ensuring preservation of a special microbiological state in related devices during transport and storage.

26. Providing an adequate level of intrinsic immunity to electromagnetic disturbance to enable devices to operate as intended.

27. Avoiding, as far as possible, the risk of accidental electric shocks during normal use during standard installation and maintenance.

28. Expressing values numerically in commonly accepted, standardized units, easily understood by the users of the device.

29. Protecting the patient and user against mechanical risks e.g. related to resistance to movement, instability and moving parts.

30. Minimizing all possible risks from terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle.

31. Preventing potentially dangerous temperatures being attained by accessible parts of the devices (excluding parts/areas intended to supply heat or reach given temperatures) and their surroundings under normal use.

32. Enabling delivered amounts of energy or substances to be set and maintained accurately in devices supplying these to the patient to guarantee safety.

33. Providing means of preventing and/or indicating any inadequacies in the delivered amount and preventing the accidental release of dangerous levels of energy or substances which could pose a danger.

34. Ensuring skills and the means available to users and the influence resulting from variation that can reasonably be anticipated in user's technique and environment in use of device.

35. Allowing user to verify at the time of use, that the device product will perform as intended.

36. Sterilization by appropriate, validated methods in sterile devices or those having a special microbiological state.

37. Manufacturing in appropriately controlled conditions of sterile devices.

38. Ensuring that clinical investigations on human subjects are carried out in accordance with the spirit of the Helsinki Declaration.

Packaging and labeling

1. Ensuring sterility of related devices is maintained when placed on the market and during transport and storage conditions by:
    - Packing in a non-reusable pack.
    - Adopting appropriate procedures.
2. Ensuring no deterioration of non-sterile devices by the following:
    - Packaging keeps device at stipulated level of cleanliness.
    - Minimizing risk of microbial contamination of devices to be sterilized before use with suitable packaging compatible with sterilization method.
3. Distinguishing between identical/similar sterile and nonsterile devices by appropriate packaging and/or labeling.
4. Ensuring that operating instructions for devices emitting radiation provide detailed information on the nature of the emitted radiation, means of protecting the patient and the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.
5. Providing users with the easily understood information needed to use the device safely and to ensure the intended performance, taking into account their training and knowledge.

APPENDIX C

The Open Source Definition

Bruce Perens wrote the first draft of this document as "The Debian Free Software Guidelines", and refined it using the comments of the Debian developers in a month-long e-mail conference in June, 1997. He removed the Debian-specific references from the document to create the "Open Source Definition."

Introduction

Open source doesn't just mean access to the source code. The distribution terms of open-source software must comply with the following criteria:

1. **Free Redistribution**
   The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale.

2. **Source Code**
   The program must include source code, and must allow distribution in source code as well as compiled form. Where some form of a product is not distributed with source code, there must be a well-publicized means of obtaining the source code for no more than a reasonable reproduction cost preferably, downloading via the Internet without charge. The source code must be the preferred form in which a programmer would modify the program. Deliberately obfuscated source code is not allowed. Intermediate forms such as the output of a preprocessor or translator are not allowed.

3. **Derived Works**
   The license must allow modifications and derived works, and must allow

them to be distributed under the same terms as the license of the original software.

4. **Integrity of the Author's Source Code**
   The license may restrict source-code from being distributed in modified form only if the license allows the distribution of "patch files" with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software.

5. **No discrimination Against Persons or Groups**
   The license must not discriminate against any person or group of persons.

6. **No Discrimination Against Field of Endeavor**
   The license must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research.

7. **Distribution of license**
   The rights attached to the program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties.

8. **License Must not be Specific to product**
   The rights attached to the program must not depend on the program's being part of a particular software distribution. If the program is extracted from that distribution and used or distributed within the terms of the program's license, all parties to whom the program is redistributed should have the same rights as those that are granted in conjunction with the original software distribution.

9. **License must not Restrict Other Software**
   The license must not place restrictions on other software that is distributed along with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open-source software.

10. **License must be Technology-Neutral**
    No provision of the license may be predicated on any individual technology or style of interface.

Appendix D

The Open Source Hardware Definition 1.0

The Open Source Hardware (OSHW) Definition 1.0 is based on the Open Source Definition in Appendix C for Open Source Software. That definition was created by Bruce Perens and the Debian developers as the Debian Free Software Guidelines.

Introduction

Open Source Hardware (OSHW) is a term for tangible artifacts — machines, devices, or other physical things — whose design has been released to the public in such a way that anyone can make, modify, distribute, and use those things. This definition is intended to help provide guidelines for the development and evaluation of licenses for Open Source Hardware.

Hardware is different from software in that physical resources must always be committed for the creation of physical goods. Accordingly, persons or companies producing items ("products") under an OSHW license have an obligation to make it clear that such products are not manufactured, sold, warrantied, or otherwise sanctioned by the original designer and also not to make use of any trademarks owned by the original designer.

The distribution terms of Open Source Hardware must comply with the following criteria:

1. **Documentation**
   The hardware must be released with documentation including design files, and must allow modification and distribution of the design files. Where

documentation is not furnished with the physical product, there must be a well-publicized means of obtaining this documentation for no more than a reasonable reproduction cost, preferably downloading via the Internet without charge. The documentation must include design files in the preferred format for making changes, for example the native file format of a CAD program. Deliberately obfuscated design files are not allowed. Intermediate forms analogous to compiled computer code — such as printer-ready copper artwork from a CAD program — are not allowed as substitutes. The license may require that the design files are provided in fully-documented, open format(s).

2. **Scope**
   The documentation for the hardware must clearly specify what portion of the design, if not all, is being released under the license.

3. **Necessary Software**
   If the licensed design requires software, embedded or otherwise, to operate properly and fulfill its essential functions, then the license may require that one of the following conditions are met:

   - The interfaces are sufficiently documented such that it could reasonably be considered straightforward to write open source software that allows the device to operate properly and fulfill its essential functions. For example, this may include the use of detailed signal timing diagrams or pseudocode to clearly illustrate the interface in operation
   - The necessary software is released under an OSI-approved open source license.

4. **Derived Works**
   The license shall allow modifications and derived works, and shall allow them to be distributed under the same terms as the license of the original work. The license shall allow for the manufacture, sale, distribution, and use of products created from the design files, the design files themselves, and derivatives thereof.

5. **Free Redistribution**
   The license shall not restrict any party from selling or giving away the project documentation. The license shall not require a royalty or other fee for such sale. The license shall not require any royalty or fee related to the sale of derived works.

6. **Attribution**
   The license may require derived documents, and copyright notices associated with devices, to provide attribution to the licensors when distributing design files, manufactured products, and/or derivatives thereof. The license may require that this information be accessible to the end-user using the device normally, but shall not specify a specific format of display. The license may require derived works to carry a different name or version number from the original design.

7. **No Discrimination Against Persons or Groups**
   The license must not discriminate against any person or group of persons.

8. **No Discrimination Against Field of Endeavor**
   The license must not restrict anyone from making use of the work (including manufactured hardware) in a specific field of endeavor. For example, it must not restrict the hardware from being used in a business, or from being used in nuclear research.

9. **Distribution of License**
   The rights granted by the license must apply to all to whom the work is redistributed without the need for execution of an additional license by those parties.

10. **License Must not be Specific to a Product**
    The rights granted by the license must not depend on the licensed work being part of a particular product. If a portion is extracted from a work and used or distributed within the terms of the license, all parties to whom that work is redistributed should have the same rights as those that are granted for the original work.

11. **License must not Restrict Other Hardware or Software**
    The license must not place restrictions on other items that are aggregated with the licensed work but not derivative of it. For example, the license must not insist that all other hardware sold with the licensed item be open source, nor that only open source software be used external to the device.

12. **License must be Technology-Neutral**
    No provision of the license may be predicated on any individual technology, specific part or component, material, or style of interface or use thereof.

APPENDIX E

Arduino Source Code

```
#include <SoftwareSerial.h>
#include "MLX90615.h"
#include <I2cMaster.h>

#define rxpin 0
#define txpin 1
#define SDA_PIN 2   //define the SDA pin
#define SCL_PIN 3   //define the SCL pin

const int buttonPin = 7;     // the number of the
   pushbutton pin
const int ledPin =  8;      // the number of the LED pin

SoftI2cMaster i2c(SDA_PIN, SCL_PIN);
MLX90615 mlx90615(DEVICE_ADDR, &i2c);

SoftwareSerial bluetooth(rxpin, txpin);

// variables will change:
int buttonState = 0;         // variable for reading the
   pushbutton status
int ledState = 0;

void setup() {
Serial.begin(9600);
Serial1.begin(9600);
```

```
// initialize the LED pin as an output:
pinMode(ledPin, OUTPUT);
// initialize the pushbutton pin as an input:
pinMode(buttonPin, INPUT);
}

void loop() {
// read the state of the pushbutton value:
buttonState = digitalRead(buttonPin);
if (buttonState == HIGH) {
// turn LED on:
digitalWrite(ledPin, HIGH);
ledState = digitalRead(ledPin);
Serial.print("Object temperature: ");
Serial.println(mlx90615.getTemperature(
   MLX90615_OBJECT_TEMPERATURE));
Serial.print("Ambient temperature: ");
Serial.println(mlx90615.getTemperature(
   MLX90615_AMBIENT_TEMPERATURE));
Serial1.println(mlx90615.getTemperature(
   MLX90615_OBJECT_TEMPERATURE));
delay(1000);
} else {
// turn LED off:
digitalWrite(ledPin, LOW);
}
}
```

APPENDIX F

Android Application Source Code

Project parameters of Android Application:

- Hardware requirements: Smartphone Android with Bluetooth connection;
- Minimal operative system: 2.2 Froyo (API 8);
- Target operative system: 4.2.2 Jelly Bean (API 17).

Main Activity

```
import java.io.IOException;
import java.io.InputStream;
import java.io.OutputStream;
import java.util.UUID;
import android.app.Activity;
import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;
import android.bluetooth.BluetoothSocket;
import android.content.Intent;
import android.os.Bundle;
import android.os.Handler;
import android.widget.TextView;
import android.widget.Toast;
```

```
public class MainActivity extends Activity {

    TextView txtString, txtStringLength, sensorView1;
    Handler bluetoothIn;

    final int handlerState = 0;    //used to identify
handler message
    private BluetoothAdapter btAdapter = null;
    private BluetoothSocket btSocket = null;
    private StringBuilder recDataString = new
StringBuilder();
    int cont = 0;
    private ConnectedThread mConnectedThread;

    // SPP UUID service
    private static final UUID BTMODULEUUID = UUID.
fromString("00001101-0000-1000-8000-00805F9B34FB");

    // String for MAC address
    private static String address;

    @Override
    public void onCreate(Bundle savedInstanceState) {
    super.onCreate(savedInstanceState);
    setContentView(R.layout.relativelayout);

    //Link the buttons and textViews to respective
views
    txtString = (TextView) findViewById(R.id.txtString)
;
    txtStringLength = (TextView) findViewById(R.id.
testView1);
    sensorView1 = (TextView) findViewById(R.id.
sensorView1);
    sensorView1.setText(R.string.premi);
```

```
        btAdapter = BluetoothAdapter.getDefaultAdapter();
// get Bluetooth adapter
        checkBTState();
        }

        private BluetoothSocket createBluetoothSocket(
BluetoothDevice device) throws IOException {

        return  device.createRfcommSocketToServiceRecord(
BTMODULEUUID);
        //creates secure outgoing connecetion with BT
device using UUID
        }

        @Override
        public void onResume() {
        super.onResume();

        //Get MAC address from DeviceListActivity via
intent
        Intent intent = getIntent();

        //Get the MAC address from the DeviceListActivty
via EXTRA
        address = intent.getStringExtra(DeviceListActivity.
EXTRA_DEVICE_ADDRESS);

        //create device and set the MAC address
        BluetoothDevice device = btAdapter.getRemoteDevice(
address);

        try {
        btSocket = createBluetoothSocket(device);
        } catch (IOException e) {
        Toast.makeText(getBaseContext(), "Socket creation
failed", Toast.LENGTH_LONG).show();
        }
```

```
        // Establish the Bluetooth socket connection.
        try {
        btSocket.connect();
        Toast.makeText(getBaseContext(), "The device is
connected", Toast.LENGTH_SHORT).show();
        } catch (IOException e) {
        try {
        btSocket.close();
        Toast.makeText(getBaseContext(), "The device is not
 connected", Toast.LENGTH_LONG).show();
        Intent i = new Intent(MainActivity.this,
DeviceListActivity.class);
        startActivity(i);
        } catch (IOException e2) {
        Toast.makeText(getBaseContext(), "An unknown error
is occurred", Toast.LENGTH_LONG).show();
        Intent i = new Intent(MainActivity.this,
DeviceListActivity.class);
        startActivity(i);
        }
        }
        mConnectedThread = new ConnectedThread(btSocket);
        mConnectedThread.start();
        //I send a character when resuming.beginning
transmission to check device is connected
        //If it is not an exception will be thrown in the
write method and finish() will be called
        try {
        mConnectedThread.write("x");
        } catch (Exception e) {
        Toast.makeText(getBaseContext(), "Problems during
connection", Toast.LENGTH_LONG).show();
        }

        bluetoothIn = new Handler() {
        public void handleMessage(android.os.Message msg) {
        if (btSocket.isConnected() == false){
```

```
      Toast.makeText(getBaseContext(), "The device is
disconnected now", Toast.LENGTH_LONG).show();
      }
      if (msg.what == handlerState) { //if message is
what we want
      cont = cont + 1;
      String readMessage = (String)msg.obj;
      recDataString.append(readMessage);
      txtString.setText("Data Received");
      if (cont == 2) {
      String sensor1 = recDataString.toString();
      //update the textviews with sensor values
      sensorView1.setText(" Temperature = " + sensor1 + "
 C");
      recDataString.delete(0, recDataString.length());
      cont = 0;
      };
      } else {
      Toast.makeText(getBaseContext(), "A problem in the
connection is occurred", Toast.LENGTH_LONG).show();
      }
      }
      };
      }

      @Override
      public void onPause()
      {
      super.onPause();
      try
      {
      //Don't leave Bluetooth sockets open when leaving
activity
      btSocket.close();
      } catch (IOException e2) {
 Toast.makeText(getBaseContext(), "A problem in the
disconnection is occurred", Toast.LENGTH_LONG).show();
```

```
        }
        }

        //Checks that the Android device Bluetooth is
available and prompts to be turned on if off
        private void checkBTState() {

        if(btAdapter==null) {
        Toast.makeText(getBaseContext(), "Device does not
support bluetooth", Toast.LENGTH_LONG).show();
        } else {
        if (btAdapter.isEnabled()) {
        } else {
        Intent enableBtIntent = new Intent(BluetoothAdapter
.ACTION_REQUEST_ENABLE);
        startActivityForResult(enableBtIntent, 1);
        }
        }
        }

        //create new class for connect thread
        private class ConnectedThread extends Thread {
        private final InputStream mmInStream;
        private final OutputStream mmOutStream;

        //creation of the connect thread
        public ConnectedThread(BluetoothSocket socket) {
        InputStream tmpIn = null;
        OutputStream tmpOut = null;

        try {
        //Create I/O streams for connection
        tmpIn = socket.getInputStream();
        tmpOut = socket.getOutputStream();
        } catch (IOException e) { }

        mmInStream = tmpIn;
```

```
        mmOutStream = tmpOut;
        }

        public void run() {
        byte[] buffer = new byte[256];
        int bytes;
        // Keep looping to listen for received messages
        while (true) {
        try {
        bytes = mmInStream.read(buffer);            //read
bytes from input buffer
        String readMessage = new String(buffer, 0, bytes);
        // Send the obtained bytes to the UI Activity via
handler
        bluetoothIn.obtainMessage(handlerState, bytes, -1,
readMessage).sendToTarget();
        } catch (IOException e) {
        break;
        }
        }
        }

        public void write(String input) {
        byte[] msgBuffer = input.getBytes();           //
converts entered String into bytes
        try {
        mmOutStream.write(msgBuffer);                //
write bytes over BT connection via outstream
        } catch (IOException e) {
        //if you cannot write, close the application
        Toast.makeText(getBaseContext(), "Connection
Failure", Toast.LENGTH_LONG).show();
        finish();
        }
        }
        }
        }
```

Device List Activity

```
import java.io.IOException;
import java.util.Set;
import android.app.Activity;
import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;
import android.bluetooth.BluetoothSocket;
import android.content.Intent;
import android.os.Bundle;
import android.util.Log;
import android.view.View;
import android.widget.AdapterView;
import android.widget.ArrayAdapter;
import android.widget.Button;
import android.widget.ListView;
import android.widget.TextView;
import android.widget.Toast;
import android.widget.AdapterView.
OnItemClickListener;


public class DeviceListActivity extends Activity {
// Debugging for LOGCAT
private static final String TAG = "
DeviceListActivity";
private static final boolean D = true;


// declare button for launching website and
textview for connection status
Button tlbutton;
TextView textView1;

// EXTRA string to send on to mainactivity
public static String EXTRA_DEVICE_ADDRESS = "
```

```
device_address";

    // Member fields
    private BluetoothAdapter mBtAdapter;
    private ArrayAdapter<String>
mPairedDevicesArrayAdapter;

    @Override
    protected void onCreate(Bundle savedInstanceState)
{
    super.onCreate(savedInstanceState);
    setContentView(R.layout.activity_device_list);

    }

    @Override
    public void onResume()
    {
    super.onResume();
    //***************
    checkBTState();

    textView1 = (TextView) findViewById(R.id.connecting
);
    textView1.setTextSize(40);
    textView1.setText(" ");

    // Initialize array adapter for paired devices
    mPairedDevicesArrayAdapter = new ArrayAdapter<
String>(this, R.layout.device_name);

    // Find and set up the ListView for paired devices
    ListView pairedListView = (ListView) findViewById(R
.id.paired_devices);
    pairedListView.setAdapter(
mPairedDevicesArrayAdapter);
    pairedListView.setOnItemClickListener(
```

```
mDeviceClickListener);

     // Get the local Bluetooth adapter
     mBtAdapter = BluetoothAdapter.getDefaultAdapter();

     // Get a set of currently paired devices and append
 to 'pairedDevices'
     Set<BluetoothDevice> pairedDevices = mBtAdapter.
getBondedDevices();

     // Add previosuly paired devices to the array
     if (pairedDevices.size() > 0) {
     findViewById(R.id.title_paired_devices).
setVisibility(View.VISIBLE);//make title viewable
     for (BluetoothDevice device : pairedDevices) {
     mPairedDevicesArrayAdapter.add(device.getName() + "
\n" + device.getAddress());
     }
     } else {
     String noDevices = getResources().getText(R.string.
none_paired).toString();
     mPairedDevicesArrayAdapter.add(noDevices);
     }
     }

     // Set up on-click listener for the list (nicked
this - unsure)
     private OnItemClickListener mDeviceClickListener =
new OnItemClickListener() {
     public void onItemClick(AdapterView<?> av, View v,
int arg2, long arg3) {

     textView1.setText(R.string.connect);
     // Get the device MAC address, which is the last 17
 chars in the View
     String info = ((TextView) v).getText().toString();
     String address = info.substring(info.length() - 17)
```

```
;

      // Make an intent to start next activity while
taking an extra which is the MAC address.
      Intent i = new Intent(DeviceListActivity.this,
MainActivity.class);
      i.putExtra(EXTRA_DEVICE_ADDRESS, address);
      startActivity(i);
      }
      };

      private void checkBTState() {
      // Check device has Bluetooth and that it is turned
 on
      mBtAdapter=BluetoothAdapter.getDefaultAdapter();
      if(mBtAdapter==null) {
      Toast.makeText(getBaseContext(), "Device does not
support Bluetooth", Toast.LENGTH_SHORT).show();
      } else {
      if (mBtAdapter.isEnabled()) {
      Log.d(TAG, "...Bluetooth ON...");
      } else {
      //Prompt user to turn on Bluetooth
      Intent enableBtIntent = new Intent(BluetoothAdapter
.ACTION_REQUEST_ENABLE);
      startActivityForResult(enableBtIntent, 1);
      }
      }
      }
      }
```

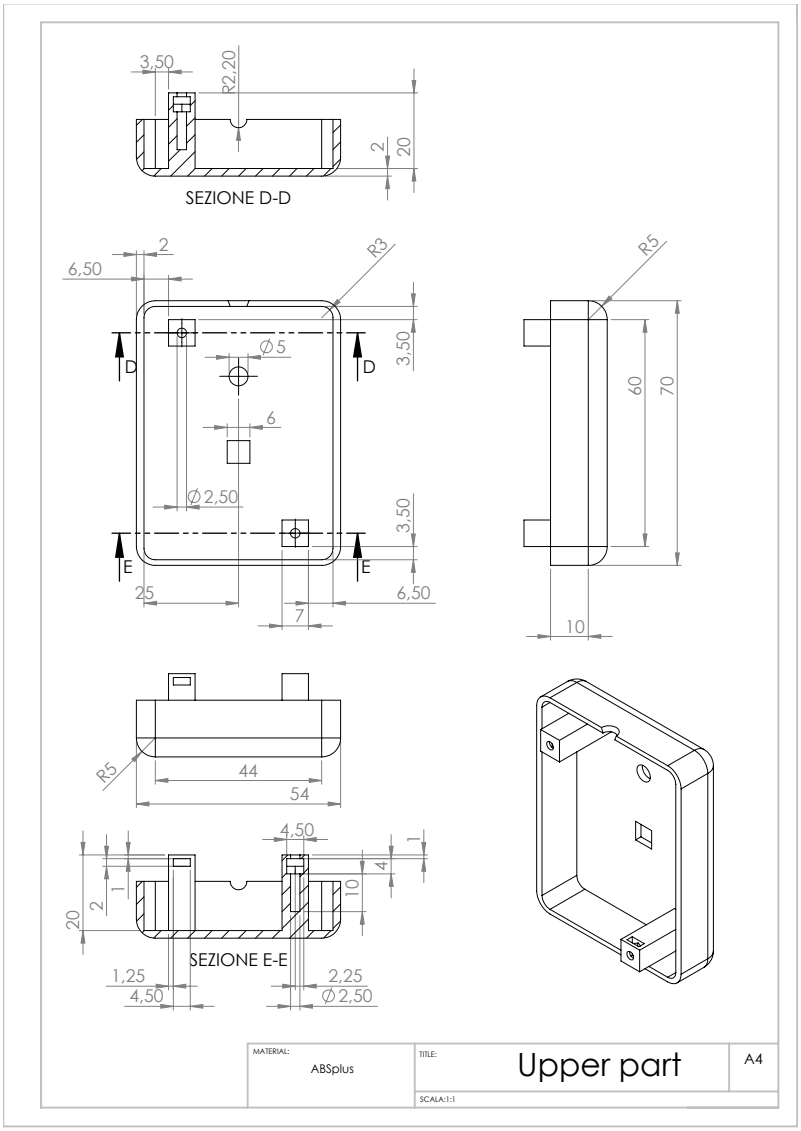
Android Manifest

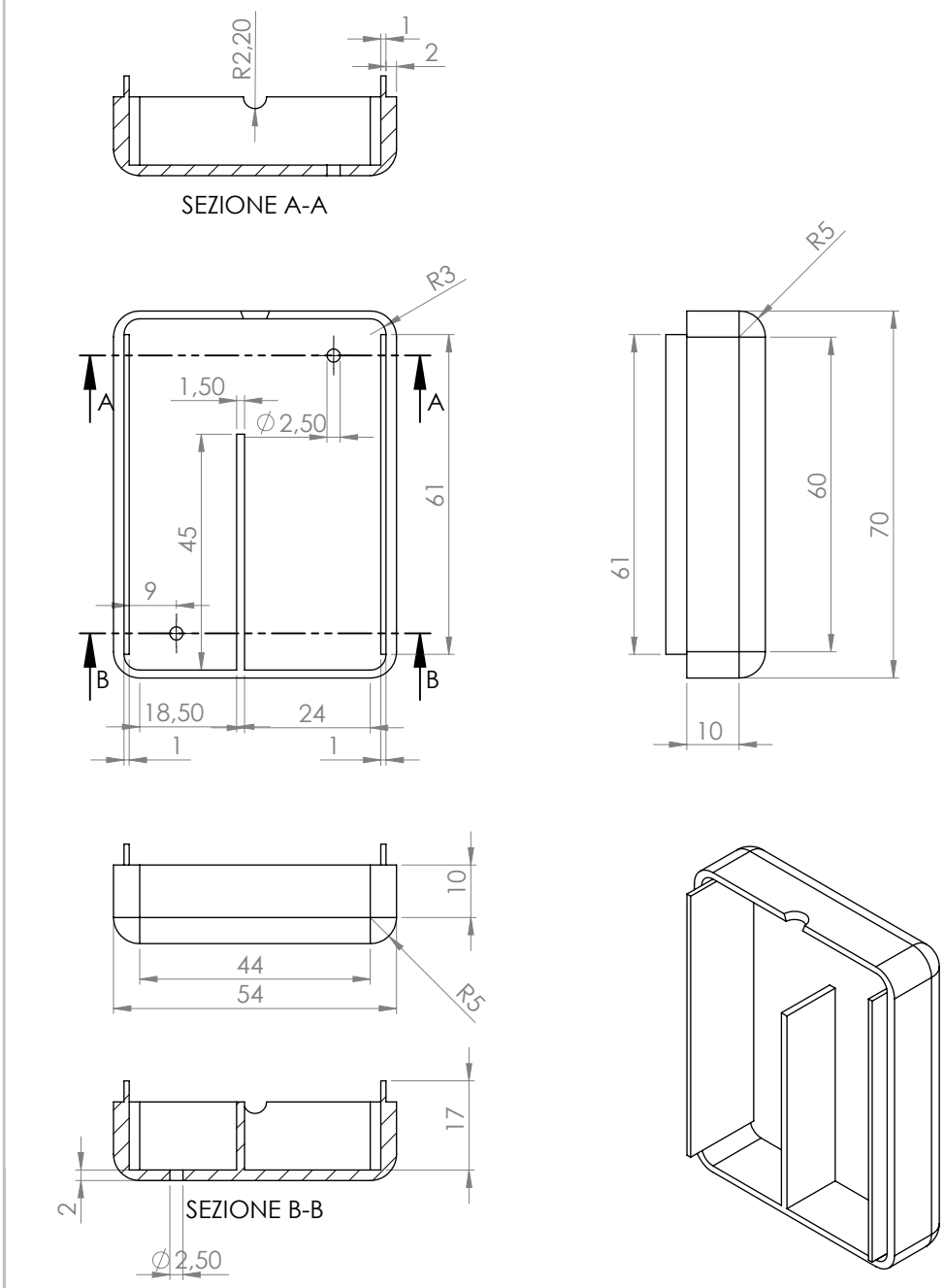
```
      <manifest xmlns:android="http://schemas.android.com
/apk/res/android"
      package="com.example.licia.thermometer">
      android:versionCode="1"
```

```
      android:versionName="1.0" >

      <uses-sdk
      android:minSdkVersion="8"
      android:targetSdkVersion="17" />
      <uses-permission android:name="android.permission.
BLUETOOTH"/>
      <uses-permission android:name="android.permission.
BLUETOOTH_ADMIN"/>

      <application
      android:allowBackup="true"
      android:icon="@mipmap/ic_launcher"
      android:label="@string/app_name"
      android:supportsRtl="true"
      android:theme="@style/AppTheme">
      <activity
      android:name=".MainActivity"
      android:label="@string/app_name"
      android:screenOrientation="portrait"  >

      </activity>
      <activity
      android:name=".DeviceListActivity"
      android:label="@string/app_name"
      android:screenOrientation="portrait" >
      <intent-filter>
      <action android:name="android.intent.action.MAIN"
/>

      <category android:name="android.intent.category.
LAUNCHER" />
      </intent-filter>
      </activity>
      </application>
      </manifest>
```

APPENDIX G

Design of thermometer




R2,20
1
2
SEZIONE A-A
R3
A
A
1,50
∅2,50
61
45
9
B
B
18,50
24
1
1
R5
61
60
70
10
10
44
54
R5
17
2
SEZIONE B-B
∅2,50
MATERIAL:
ABSplus
TITLE:
Lower part
A4
SCALA:1:1

APPENDIX H

OpenSCAD Code for frame

The required parameters to manufacture a custom made spectacles are those in that have "change it" into the comment.

```
//Spectacles frame

$fn=1000;  //change resolution, effects rendertime.
   Suggested resolition is 1000 (change it)

total_length = 140;   // (change it)
dia_lens =40;           //in mm , diameter of lens, (
   beteween 40-70 mm) (change it)
r_lens=dia_lens/2;

bridge_side=20;
h_glasses = 5;
h_lens = 2;

thick_glasses=(total_length-4*r_lens-bridge_side)/4;

sag = 5;
thick_bridge = 4;

ri_bridge = (pow(0.5*bridge_side,2))/(2*sag);
re_bridge= ri_bridge+thick_bridge;
racc=1.5;
```

```
l=4;         //length hinge holder (in mm)
d=7;        //depth hinge holder (in mm)
border = dia_lens+4;


module lenshouder()
{
    difference()
    {
        cylinder(h=2*h_lens,r=(border+3)/2);
        translate([0,0,h_lens])
        cylinder(h=h_lens,r=border/2);
        cylinder(h=h_lens,r=dia_lens/2);
    }
    difference()
    {
        difference()
        {
            translate([-3.5,border/2,0])
            cube([7,12,2]);
            translate([-2,(border/2)+2.5,0.5])
            cube([l,d,thick_bridge-2]);
        }
        translate([0,(border/2)+8,0])
        difference()
        {
            cylinder(h=thick_bridge-2,r=d);
            cylinder(h=thick_bridge-2,r=d/2);
            translate([0,-5,0])
            cube([20,10,10], center = true);
        }
} }


module connectors ()
{
    difference(){
```

```
        difference(){
true);
minkowski(){
    translate([0,0,racc])
    cylinder(h=thick_bridge-2*racc,r=re_bridge);
    sphere(racc);
    }
    cylinder(h=thick_bridge+10,r=ri_bridge, center = true
    }
    translate([0,-(ri_bridge),0])
    cube(size=[4*re_bridge,4*(ri_bridge-sag),
20],center=true);
                }
}


 union(){
lenshouder();
rotate([0,0,180])translate([0,(border+2)+bridge_side,
0])lenshouder();
translate([0,-(((border/2)+bridge_side/2)+1),
0])rotate([0,0,90])connectors();
 }


 translate([0,0,1.5])
 cylinder(h=2.5,r=border/2);
 cylinder(h=1.5,r=dia_lens/2);
 translate([0,-((border+2)+bridge_side),0])
 translate([0,0,1.5])
 cylinder(h=2.5,r=border/2);
 translate([0,-((border+2)+bridge_side),0])
 cylinder(h=1.5,r=dia_lens/2);
 }
```

```
// Rigth sidepiece

$fn=1000;  //change resolution, effects rendertime.
   Suggested resolition is 1000 (change it)

dia_lens = 40;  //in mm , diameter of lens, (beteween 40-70
    mm)  (change it)

l=4; //length hinge holder (in mm)
d=7; //depth hinge holder (in mm)

border = dia_lens+4;

sidepiece = 90;     (change it)
sidepiece_ear = 40;     (change it)


union(){
difference()
{
difference()
{
union()
{
translate([-3.5,border/2,0])
cube([7,12,2]);
translate([-2,(border/2)+2.5,1.5])
cube([l,d,thick_bridge-2]);
}
translate([0,(border/2)+8,0])
difference()
{
cylinder(h=thick_bridge-2,r=d);
cylinder(h=thick_bridge-2,r=d/2);
translate([0,-5,0])
cube([20,10,10], center = true);
```

```
}
}
cylinder(h=4,r=(border+3)/2);
}
translate([0,(border+4)/2,0])
minkowski(){
union(){
translate([0,5,-sidepiece/2])
cylinder(h=sidepiece, r=1, center=true);
translate([0,5,-sidepiece])
rotate([0,200,0])
cylinder(h=sidepiece_ear,r=1);
}
sphere(1);
}
}

// Left sidepiece

$fn=1000;  //change resolution, effects rendertime.
   Suggested resolition is 1000 (change it)

dia_lens = 40;  //in mm , diameter of lens, (beteween 40-70
    mm)   (change it)

l=4; //length hinge holder (in mm)
d=7; //depth hinge holder (in mm)

border = dia_lens+4;

sidepiece = 90;   (change it)
sidepiece_ear = 4;   (change it)

union(){
    difference()
        {
        difference()
        {
```

```
union()
{
translate([-3.5,border/2,0])
cube([7,12,2]);
translate([-2,(border/2)+2.5,1.5])
cube([l,d,thick_bridge-2]);
}
translate([0,(border/2)+8,0])
difference()
{
cylinder(h=thick_bridge-2,r=d);
cylinder(h=thick_bridge-2,r=d/2);
translate([0,-5,0])
cube([20,10,10], center = true);
}
}
cylinder(h=4,r=(border+3)/2);
}
translate([0,(border+4)/2,0])
minkowski(){
union(){
translate([0,5,-sidepiece/2])
cylinder(h=sidepiece, r=1, center=true);
translate([0,5,-sidepiece])
rotate([0,-200,0])
cylinder(h=sidepiece_ear,r=1);
}
sphere(1);
}
}
```

APPENDIX I

OpenSCAD Code for lenses

The required parameters to manufacture a custom made lenses are those in that have "change it" into the comment.

```
//Meniscus lens

$fn=1000;  //change resolution, effects rendertime.
   Suggested resolition is 1000 (change it)

D = 3.00;   // dioptric (cheange how you prefere) (change
   it)
n = 1.5304; //refractive index clear resin

D1 = 5.00;
D2 = D-D1;

R1= ((n-1)/D1)*1000;
R2= ((1-n)/D2)*1000;

dia_lens= 50;  //in mm , diameter of lens, (beteween 40-70
   mm)   (change it)
r_lens = dia_lens/2;
h_lens = 2;  //in mm, thickness of lens

sag1 = R1-sqrt(pow(R1,2)-pow(0.5*dia_lens,2));
translate1 = R1 - sag1;
```

```
sag2 = R2-sqrt(pow(R2,2)-pow(0.5*dia_lens,2));
translate2 = R2 - sag2;

module lens()
{
difference(){
union(){
cylinder(h=h_lens,r=r_lens);
translate([0,0,h_lens])

difference () {
translate([0,0,-translate1])
sphere(R1);
translate([0,0,-R1])
cube(2*R1,center=true);
}
}
translate([0,0,-translate2])
sphere(R2);
}
}

module thick()
{
difference()
{
cylinder(h=h_lens-0.5,r=r_lens+2);
cylinder(h=4*h_lens,r=r_lens-0.5,center=true);
}
}

union()
{
thick();
translate([0,0,h_lens-0.5])
lens();
}
```

APPENDIX J

Ultrasound evaluation test

Ultrasound

Evaluation test

1. **What is sound?**

_____

_____

_____

2. **Define the acoustic impedance. (write the equation)**

3. **Which is the SI unit of acoustic impedance?**
Mark only one oval.

- ◯ kg/m2/s
- ◯ kg/m2*s
- ◯ l*m2/s
- ◯ g/cm/s

4. **Two sound waves have a frequency double the other. The wave with greater frequency has :**
Mark only one oval.

- ◯ Double speed
- ◯ Double speed and wavelength half
- ◯ Half wavelength
- ◯ Double wavelength
- ◯ Quadruple wavelength

5. **Medical ultrasound is usual of the order of:**
Mark only one oval.

- ◯ MEGAHERTZ (MHz)
- ◯ GIGAHERTZ (GHz)
- ◯ HERTZ (Hz)
- ◯ None of the above

6. **Define the characteristics of the probes.**
Mark only one oval per row.

	Low frequency probe	High frequency probe
Long wavelength		
Longer near zone		
Less sensitivity		
Less beam spread		
High sensitivity		
More attenuation		
Short Wavelength		
Better penetration		
Less attenuation		
Shorter penetration		
Longer dead zone		
Shorter dead zone		
Shorter near zone		
Shorter penetration		

7. **Ultrasound waves are produced using which type of effect?**
Mark only one oval.

- Piezoelectric effect
- Reverse piezoelectric effect

8. **Image 1. Define the type of probe.**
Mark only one oval per row.

	Phased array Probe	Curved Probe	Linear Probe
Picture 1			
Picture 2			
Picture 3			

9. **Image 2. Which type of display is used?**
Mark only one oval per row.

	B-Mode	M-Mode	A-Mode
Type 1			
Type 2			
Type3			

10. **The Doppler effect can be used:**
Mark only one oval per row.

	True	False
to measure the blood flow		
to see bone fractures		
to measure the movement of fetal heart		
to treat tumors		

11. **Image 3. Define the type of Doppler Ultrasound**
Mark only one oval per row.

	Type 1	Type 2
Continuous Wave Doppler (CW)		
Pulsed Wave Doppler (PW)		

12. **Image 4. Define the part of the Ultrasound Equipment.**
Mark only one oval per row.

	Part 1	Part 2	Part 3	Part 4	Part 5
Various Transducers					
Screen/Display					
Portable					
Computer					
Transducer pulse controls					

APPENDIX K

X-ray evaluation test

X-Ray

Evaluation test

1. **The atomic number of an element indicates:**
   Mark only one oval.
   - ◯ Number of protons in the nucleus
   - ◯ The number of nucleons in the nucleus
   - ◯ The number of neutrons in the nucleus
   - ◯ The number of protons in the nucleus
   - ◯ The number of electrons in the most outer orbit
   - ◯ Other: _____

2. **Which is the maximum number of electrons that can be contained in the n = 2 level ?**
   Mark only one oval.
   - ◯ 4
   - ◯ 32
   - ◯ 18
   - ◯ 10
   - ◯ 8
   - ◯ Other: _____

3. **The difference between the mass number and the atomic number is :**
   Mark only one oval.
   - ◯ Number of neutrons
   - ◯ Valency
   - ◯ Number of electrons
   - ◯ Atom's charge
   - ◯ Number of protons
   - ◯ Other:

4. **X-Ray is:**
   Mark only one oval.
   - ◯ Alpha-particles
   - ◯ Protons
   - ◯ Neutrons
   - ◯ Eletctrons
   - ◯ Photons
   - ◯ Other: _____

5. **The energy of X-Ray is:**
Mark only one oval.

- ◯ directly proportional to their frequency
- ◯ Inversely proportional to their frequency
- ◯ Independent of their frequency
- ◯ Constant
- ◯ Independent of the wavelength
- ◯ Other: .....

6. **Image 1. Define the units of measurement into the box**
Mark only one oval per row.

	Box 1	Box 2	Box 3
Sievert	◯	◯	◯
Bequerel	◯	◯	◯
Gray	◯	◯	◯

7. **The electron volt (eV) is a unit of**
Mark only one oval.

- ◯ Electric charge
- ◯ Power
- ◯ Energy
- ◯ All of the above

8. **To produce X ray, electrons are accelerated to a high velocity by an electrical field and then suddenly stopped by a collision with a solid body. This body is called:**
Mark only one oval.

- ◯ Cathode
- ◯ Filament
- ◯ Target
- ◯ Generator

9. **X-ray generators produce radiation through:**
Mark only one oval.

- ◯ Bremsstrahlung processes (A)
- ◯ K-shell emmission processes (B)
- ◯ Radioactive decay
- ◯ Both A and B

10. **The "bremsstrahlung" process involves the production of ion pairs when one electron collides with another**
Mark only one oval.

- ◯ True
- ◯ False
- ◯ Other: .....

11. **Who is given credit for the discovery of X-ray?**
Mark only one oval.

- Henri Becquerel
- Wilhelm Roentgen
- Marie Curie
- Pierre Curie

12. **Radiographic contrast describe:**
Mark only one oval.

- The sharpness of lines in a radiograph
- The differences in photographic density in a radiograph
- The average photographic density in a radiograph
- The difference in density between two different radiographs

13. **X-ray and Gamma ray present a health risk because they are a form of ionizing radiation, which means that the radiation has enough energy to:**
Mark only one oval.

- Vibrate water molecules and generate heat
- Break chemical bonds
- Break physical bonds
- None of the above

14. **On a film radiograph, an area of high density in the test component will appear:**
Mark only one oval.

- Lighter than the surrounding area
- Darker than the surrounding area
- More defined than the surrounding area
- Less defined than the sorrounding area

15. **When X-ray film is developed, the portion that was exposed to radiation turns dark.**
Mark only one oval.

- True
- False

16. **When penetrating radiation is directed at a material, the radiation intensity:**
Mark only one oval.

- Decreases exponentially with increasing material thickness
- Increases linearly with increasing material thickness
- Decrease linearly with increasing material thickness
- None of the above

17. **The factor that indicates how much attenuation will take place per centimeter is known as the:**
Mark only one oval.

- Mass attenuation coefficient
- Linear attenuation coefficient
- Decay rate
- Atomic number

18. **The number of X-ray that are transmitted through a material depends on the:**
Mark only one oval.

- Energy of the photons
- Thickness of the material
- Atomic number of the material
- All of the above

19. **Collimators are used to:**
Mark only one oval.

- Reduce the radiation beam spread
- Filter the radiation beam
- Increase film latitude
- Decrease film latitude

20. **Attenuation of radiation is due to:**
Mark only one oval.

- Absorption (A)
- Scattering (B)
- Radioactive decay
- Both A and B

APPENDIX L

BME Survey

Biomedical Engineering survey

How to improve healthcare through Biomedical Engineering?

1. **Age**

2. **Profession**
   Mark only one oval.
   - ◯ Student
   - ◯ Professor
   - ◯ Physician
   - ◯ Techinician

Innovators' Summer School

Students training

3. **Express your personal opinion regarding ISS**
   use a scale from 1 to 5
   Mark only one oval.

	1	2	3	4	5	
not satisfaying	◯	◯	◯	◯	◯	very satisfaying

4. **Have you ever participated at Innovators' Summer School?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

5. **Do you think that the innovators' Summer School can help to improve Biomedical Engineering in Africa?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No
   - ◯ Perhaps

6. **Would you change something in its organization?**
   Mark only one oval.
   - ◯ Yes
   - ◯ No

7. **If "Yes", what?**
   Participation, organization, period, topics..

8. **To improve the competences of students, do you think there are other ways?**
   Mark only one oval.
   - Yes
   - No

9. **If "Yes", which?**

Repair Biomedical Devices

Technical training

10. **Would you be interest in taking part in a course where you can learn to repair biomedical devices?**
    Express your interest through a scale from 1 to 5
    Mark only one oval.

	1	2	3	4	5	
not interested						very interested

11. **If you can choose between the training finalized for designing new biomedical devices, or training for repairing old biomedical devices, which one would you choose?**
    Mark only one oval.
    - Design
    - Repair

12. **Do you think that biomedical technicians are properly prepared in Africa?**
    Express you thought through a scale from 1 to 5
    Mark only one oval.

	1	2	3	4	5	
not prepared						very prepared

13. **Do you think that the training of biomedical technicians can help to improve the level of Biomedical Engineering in Africa?**
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Perhaps

14. **In which way do you want to improve it?**

.....

.....

.....

.....

Donation of Biomedical Devices

Training to use donated devices

15. **Do you know some associations that offer biomedical equipment to African Hospitals?**
Mark only one oval.

- ◯ Yes
- ◯ No

16. **If "Yes", which hospitals and which devices?**

.....

.....

.....

.....

17. **How important is the donation of biomedical equipment for African healthcare?**
Express you personal opinion through a scale from 1 to 5
Mark only one oval.

	1	2	3	4	5	
not important	◯	◯	◯	◯	◯	very important

18. **Do you think that the technicians in the African hospital receive adequate training to use the donated equipment?**
Express your personal thought through a scale from 1 to 5
Mark only one oval.

	1	2	3	4	5	
not adequate	◯	◯	◯	◯	◯	very adequate

19. **Do you think that the donation of biomedical equipment can help to improve the level of Biomedical Engineering in Africa?**
Mark only one oval.

- ◯ Yes
- ◯ No
- ◯ Perhaps

20. **If "Yes", in which way?**

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